on the LCD display. Two readings "0.000+/-0.005" and "4.836+/-0.005" should be obtained. Record the corresponding hex readings of these two points. Move the track to both end positions, the hex codes displayed on the LCD should be within +/- 1 hex digit of the recorded hex codes. Press the enter key to advance to the size sensor calibration test.

- Size sensor calibration test:

  The Micro-Controller displays "SIZE(INCH) Y.YYY=XX".. Y.YYY is a size height measurement (in inches) for the syringe to be measured. If no syringe is loaded, the nominal height is 0.100". Correctly load TERUMO 1, 6, 25, and 60 syringes. Verify the readings on the LCD display. Refer to data sheet in Appendix E for the acceptable range for each syringe.

4.5 TROUBLE-SHOOTING GUIDE

The Trouble-shooting Chart in the appendix G can be used as a guide to help locate the probable cause of a problem. The chart is not all inclusive, and the causes of some problems may be multiple or not in the chart. The success of the trouble-shooting depends largely on the user's knowledge and experience with the pump. Please call the Service Department at Medfusion if further assistance is needed.

4.6 RETURINING YOUR PUMP FOR SERVICE

Please call Medfusion for a Return Authorization Number (RA) before sending your pump to Medfusion for service. Use the original package to ship the pump if possible. Remove the Pole clamp and Charger form the pump. There is no need to return the pole clamp and charger with the pump unless they are questionable. Please include a description (as specific or detailed as possible) regarding the problem of the pump so that we can properly and quickly service the pump.

B-D
MONO -

APPENDIX A. ASSEMBLY DRAWINGS

A.1 Final Assembly

A.2 Top Housing S/A

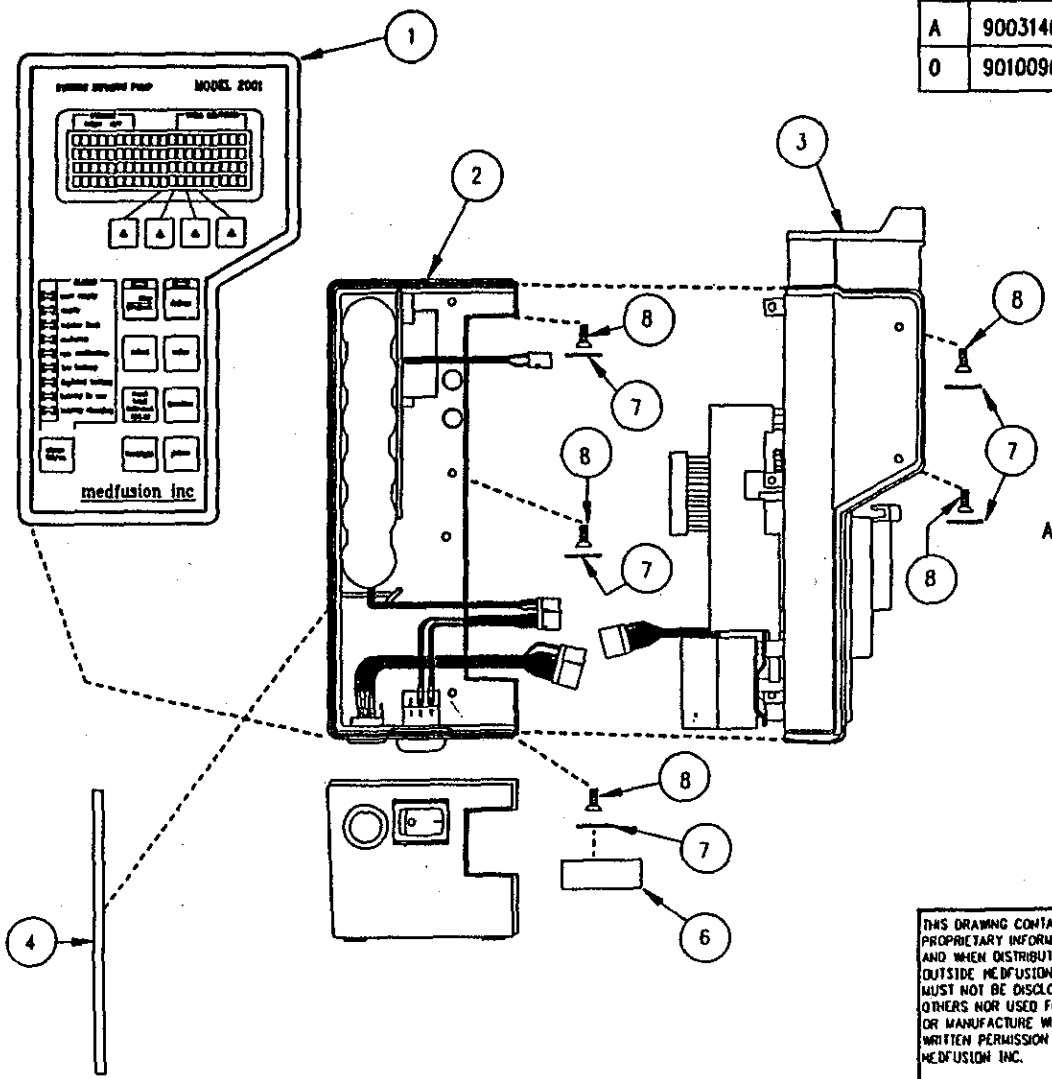
A.3 Bottom Housing S/A

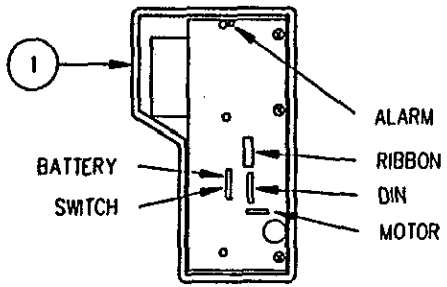
A.4 Slide Housing S/A

A.5 Slide S/A

A.6 Plunger Holder / Track S/A

REV	DCN#	DESCRIPTION OF REVISION	APPROVED	DATE
A	90031402	DELETE CHARGER AND LABEL	C. LEE	3-27-90
			R. BOOTH	3-28-90
0	90100901	ADDED INSTRUCTION LABEL		12-20-90
				1-7-91





PC BOARD CONNECTIONS

ASSEMBLY INSTRUCTIONS:

1. PLUG IN CONNECTORS FROM BOTTOM HOUSING (2) TO PCB ON TOP HOUSING. CONNECT ALARM TO PCB ON TOP HOUSING. CONNECT MOTOR AND RIBBON CABLE TO PCB ON TOP HOUSING.
2. ASSEMBLE SLIDE HOUSING SUB ASSEMBLY (3) TO TOP HOUSING SUB ASSEMBLY AND THEN ASSEMBLE INTO BOTTOM HOUSING SUB ASSEMBLY. BE SURE ROUTING WILL NOT INTERFERE WITH ASSEMBLY.
3. INSERT THREE SCREWS (8) FOR THE BOTTOM HOUSING STARTING WITH THE OUTSIDE SCREWS.
4. INSERT THE OTHER TWO SCREWS (8) INTO THE SLIDE HOUSING.
5. TIGHTEN ALL SCREWS.
6. PLACE SCREW HEAD COVERS (7) AND THE TAMPER RESISTANT LABEL (6) OVER SCREW HEAD HOLES.
7. PLACE INSTRUCTIONS (4) ON SIDE OF PUMP.

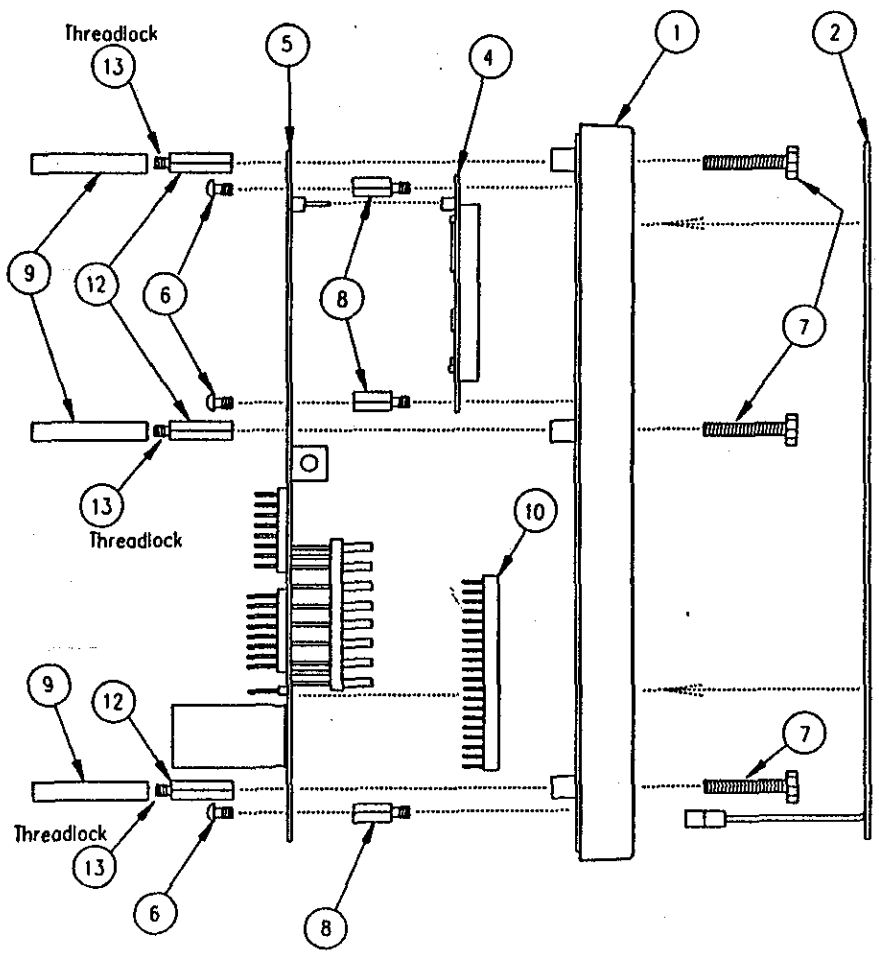
THIS DRAWING CONTAINS PROPRIETARY INFORMATION AND WHEN DISTRIBUTED OUTSIDE MEDFUSION INC. MUST NOT BE DISCLOSED TO OTHERS NOR USED FOR SALE OR MANUFACTURE WITHOUT WRITTEN PERMISSION FROM MEDFUSION INC.

DWN.	D. AMMANN	1-5-90
ENGR.	J. STEMPFLE	1-5-90
CHK	D. AMMANN	1-5-90
PROD	B. KRATOFIL	1-5-90
APVD	R. BOOTH	1-5-90

MEDFUSION INC.

DIMENSIONS ARE IN INCHES — TOLERANCES UNLESS OTHERWISE NOTED
DEC — ANGLE
FINISH: N/A — MATERIAL: N/A
TITLE: FINAL ASSEMBLY
SIZE: B — SHEET: 1 OF 1 — SCALE: NONE
PRODUCT REFERENCE: 2001 — PART NO.: 1-72-20010-0-1 — REV: 0

REV	DCN #	DESCRIPTION OF REVISION	APPROVED	DATE
1	90031402	CHANGED ITEM #9, ADDED ITEMS 12,13	C. LEE	3-22-90
			R.BOOTH	3-23-90
2	90060101	ELIMINATED LCD INSERT & GLUE	J.STEMPFLE	6-05-90
			R.BOOTH	6-06-90
2B	90092701	ADD NOTE ON STEP 1.		10-8-90
				10/10/90



ASSEMBLY INSTRUCTIONS:

1. INSERT 3 HEX HEAD SCREWS IN TOP HOUSING
   REMOVE BACKING FROM KEYPAD AND INSTALL IN TOP HOUSING
   NOTE: IF SEIKO DISPLAY IS TO BE USED,
   TRIM KEYPAD/TOP AROUND LCD DISPLAY
2. INSTALL LCD INTO TOP HOUSING.
3. INSTALL THREE MALE-FEMALE STANDOFFS
4. INSTALL PROGRAMMED MPU INTO MAIN PC BOARD
5. CONNECT KEYPAD TAIL TO MAIN PC BOARD
   INSTALL MAIN PC BOARD TO TOP HOUSING S/A
6. INSTALL THREE ROUND NYLON FEMALE STANDOFFS TO THREE BRASS HEX STANDOFFS WITH THREADLOCK. INSTALL ASSEMBLY TO HEX HEAD SCREWS. INSTALL PAN HEAD SCREWS.

THIS DRAWING CONTAINS PROPRIETARY INFORMATION AND WHEN DISTRIBUTED OUTSIDE MEDFUSION INC. MUST NOT BE DISCLOSED TO OTHERS NOR USED FOR SALE OR MANUFACTURE WITHOUT WRITTEN PERMISSION FROM MEDFUSION INC.

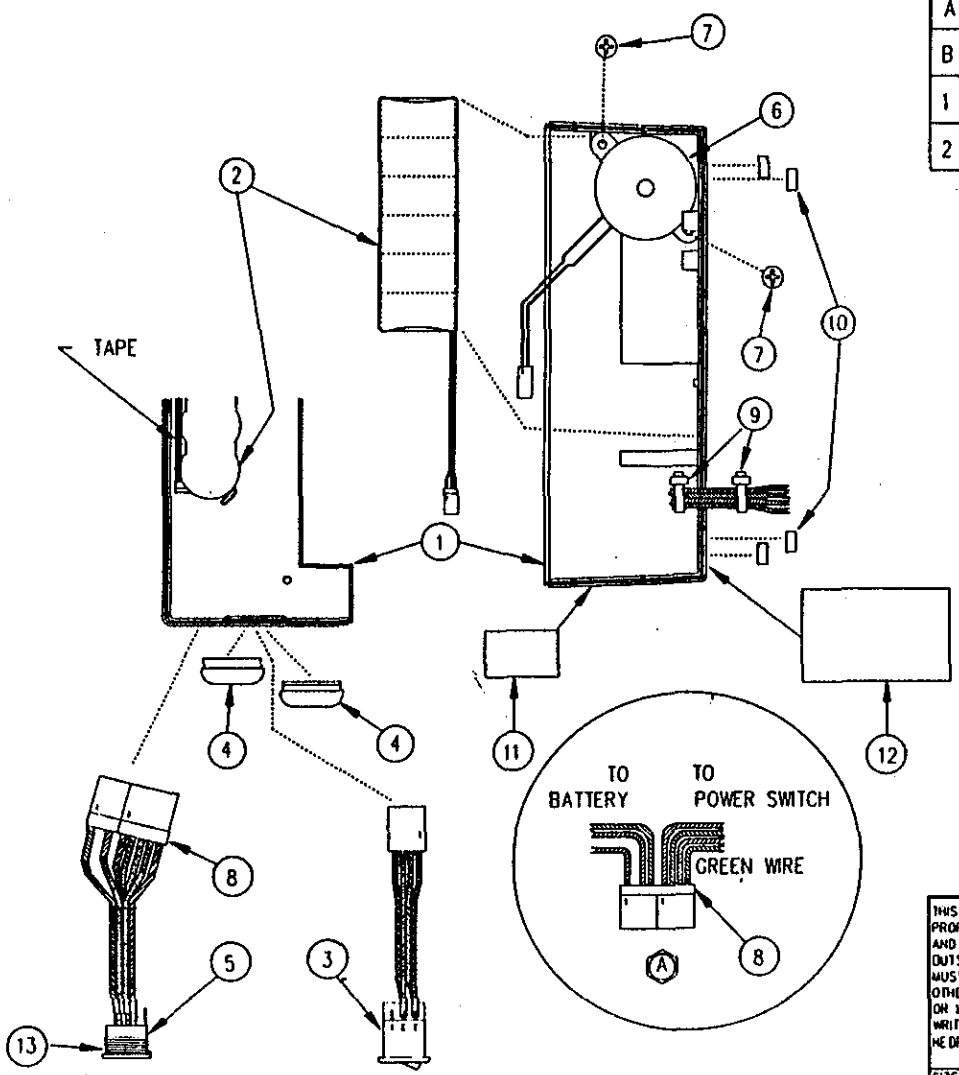
DWN	D.AMMANN	12-11-89
ENGR	L.GARCIA	12-12-89
CHK	D.AMMANN	1-05-90
PROD	B.KRATOFIL	1-05-90
APVD	R.BOOTH	1-05-90

MEDFUSION INC.

DIMENSIONS ARE IN INCHES
DEC NA
TOLERANCES UNLESS OTHERWISE NOTED
ANGLE
FINISH NA
MATERIAL NA
TITLE TOP HOUSING S/A

SIZE	SHEET	DCN #		PRODUCT REFERENCE	PART NO.	% REV
B	1 OF 1	NA	NONE	2001	1-68-20A00-0-2	B

REV	REF	DESCRIPTION OF REVISION	APPROVED	DATE
A	90031402	ADD LABEL	C. LEE	3-27-90
			R. BOOTH	3-28-90
B	90060401	DELETE ADHESIVE; ITEM 5 HAD 2 WIRES	D. AMMANN	6-20-90
			R. BOOTH	6-21-90
1	90091404	ADDED LABEL (11)	D. AMMANN	9-17-90
			R. BOOTH	9-17-90
2	91042504	REVISED ASSEMBLY INSTRUCTIONS		5-31-91
				6-10-91



ASSEMBLY INSTRUCTIONS:

1. ATTACH TWO SWITCH GUARDS (4) TO BOTTOM HOUSING.
2. INSTALL DIN RECEPTACLE SUB-ASSEMBLY (5) THROUGH THE BOTTOM OF THE BOTTOM HOUSING, AND ADD SMALL AMOUNT OF LOCTITE (13) TO THREADS. ATTACH RETAINING RING TO DIN RECEPTACLE (NOTCHES TOWARD CENTER). TIGHTEN WITH SPECIAL TOOL.
3. PRESS POWER SWITCH (3) INTO BOTTOM HOUSING. BE SURE O (OFF) ON SWITCH IS CLOSEST TO DIN RECEPTACLE.
4. PEEL OFF TAPE BACKING ON BACK OF BATTERY PACK (2), AND PLACE INTO BOTTOM HOUSING WITH CABLE ON BOTTOM OF BATTERY PACK.
5. ATTACH ALARM (6) TO BOTTOM HOUSING (1) WITH 2 SCREWS (7).
6. ADD STRAIN RELIEF (8) TO THE THE POWER SWITCH AND BATTERY CONNECTOR (BE SURE GREEN WIRE IS ON THE OUTSIDE). ADD STRAIN RELIEF (8) TO THE TWO DIN CONNECTORS.
7. USE 2 WIRE TIES (9) TO TIE THE WIRES FROM THE POWER SWITCH, DIN RECEPTACLE AND BATTERIES TOGETHER.
8. ADD FOUR FEET (10) TO BOTTOM HOUSING IN RECESS PROVIDED.
9. ADD LABELS (11) & (12)

THIS DRAWING CONTAINS PROPRIETARY INFORMATION AND WHEN DISTRIBUTED OUTSIDE MEDFUSION INC. MUST NOT BE DISCLOSED TO OTHERS NOR USED FOR SALE OR MANUFACTURE WITHOUT WRITTEN PERMISSION FROM MEDFUSION INC.

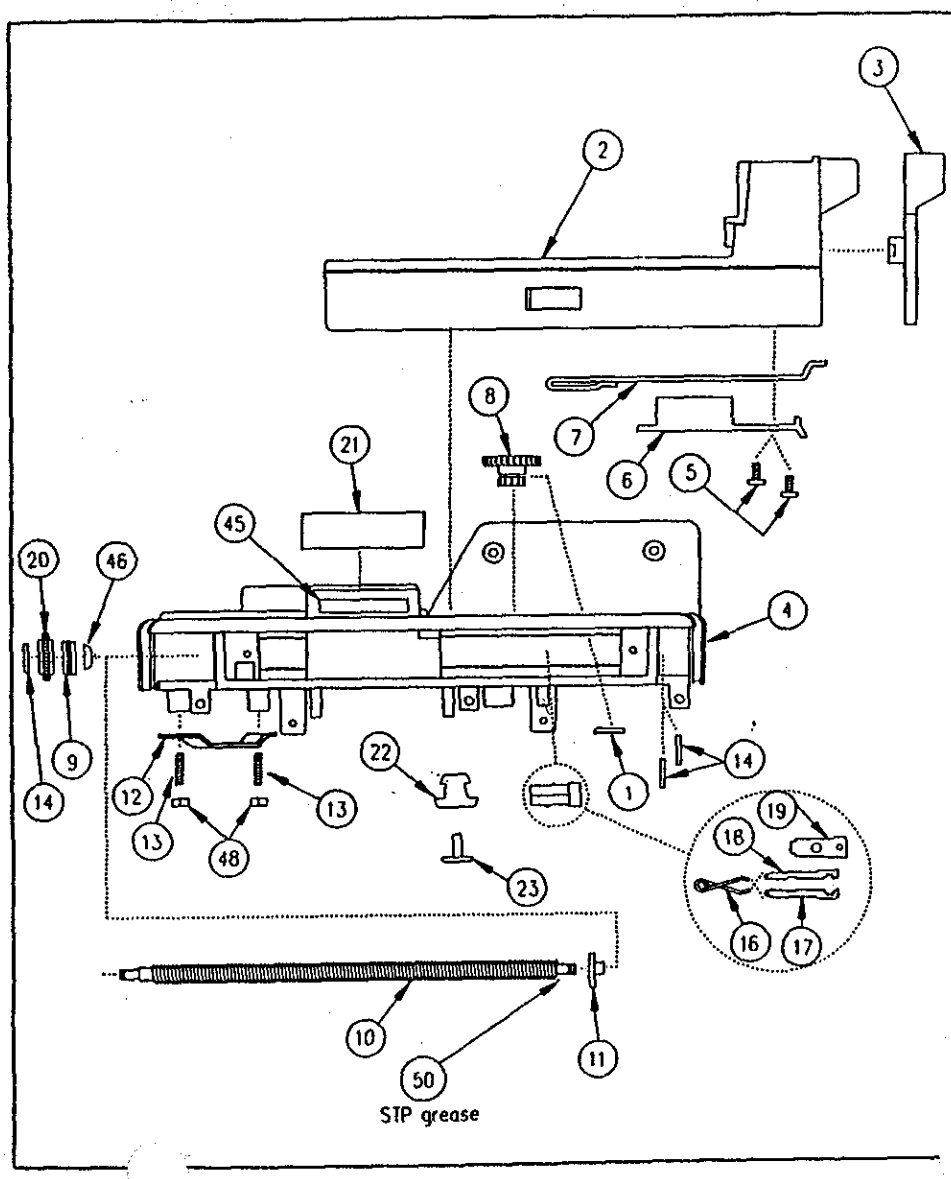
DWN	D. AMMANN	1-5-90
ENGR	C. J. LEE	1-5-90
CHK	D. AMMANN	1-5-90
PROD	B. KRATOFIL	1-5-90
APVD	R. BOOTH	1-5-90

MEDFUSION INC.

DIMENSIONS ARE IN INCHES — TOLERANCES UNLESS OTHERWISE NOTED
DEC — ANGLE
FINISH: N/A — MATERIAL: N/A
TITLE: BOTTOM HOUSING S/A
SIZE: B — SHEET: 1 OF 1 — SCALE: NONE
PRODUCT REFERENCE: 2001 — PART NO.: 1-68 20A01-0-2 — REV: D

Clutch Label

048-2000-900



REV	DCN#	DESCRIPTION OF REVISION	APPROVED	DATE
A	90072601	MADE ITEM 37 A SUB ASSEMBLY	D. AMMANN R. BOOTH	8-6-90 8-6-90
5	90110501	ADDED ADDITIONAL ITEM 14	R.BOOTH D.AMMANN	12-10-90 12-10-90
A	91060302	SAFETY WARNING ADDED	D. Ammann R. Booth	6-14-91 6-14-91

ASSEMBLY INSTRUCTIONS:

* SAFETY GLASSES REQUIRED

NOTE: All 2-56 screws are to be torqued 10 in/oz.
All 4-40 screws are to be torqued 16 in/oz.

*1. Press the cluster gear (8) through the slide top housing (4) and secure with an E-clip (1).

2. Feed transducer cable through cable seal (22), then position in slide housing. Cable length after cable seal is 1.5 inch. Secure with cable plug (23).

*3. Wearing safety glasses, assemble the clutch spring (16) onto the lower clutch (17) then onto the upper clutch (18). Do not let go of this assembly as it may spring apart. Insert this assembly through the slot in the slide top housing and into the square hole in the track assembly (2) making sure the cable does not interfer with clutch. The tabs face away from the plunger holder. Slide the clutch assembly towards the tab side and insert the clutch key (19).

4. Insert clutch actuator (7) into clutch assembly. Attach clutch lever (3) and slide clutch actuator into clutch lever. Attach clutch cover (6) and attach with two pan head screws (5).

5. Attach the motor mount (12) with two set screws (13) and two 1/4 hex female standoffs (48). Align with fixture (0-66-20003-0-X) and tighten to 10 in-lb torque.

*6. Open the clutch and insert feed screw (10). Grease (50) and install thrust washer (11) and slide the assembly till end of feed screw comes through the slide bottom. Secure with two E-clips (14).

*7. Insert water seal (46) (note orientation) then bearing (9). With bearing insertion tool (0-66-20004-0-X), press the leadscrew bearing into the slide bottom. Check turning of feed screw with tool (0-66-20005-0-X). Press the worm gear (20) over the square end of the leadscrew and secure it with an E-clip (14). Check manual operation of plunger track movement.

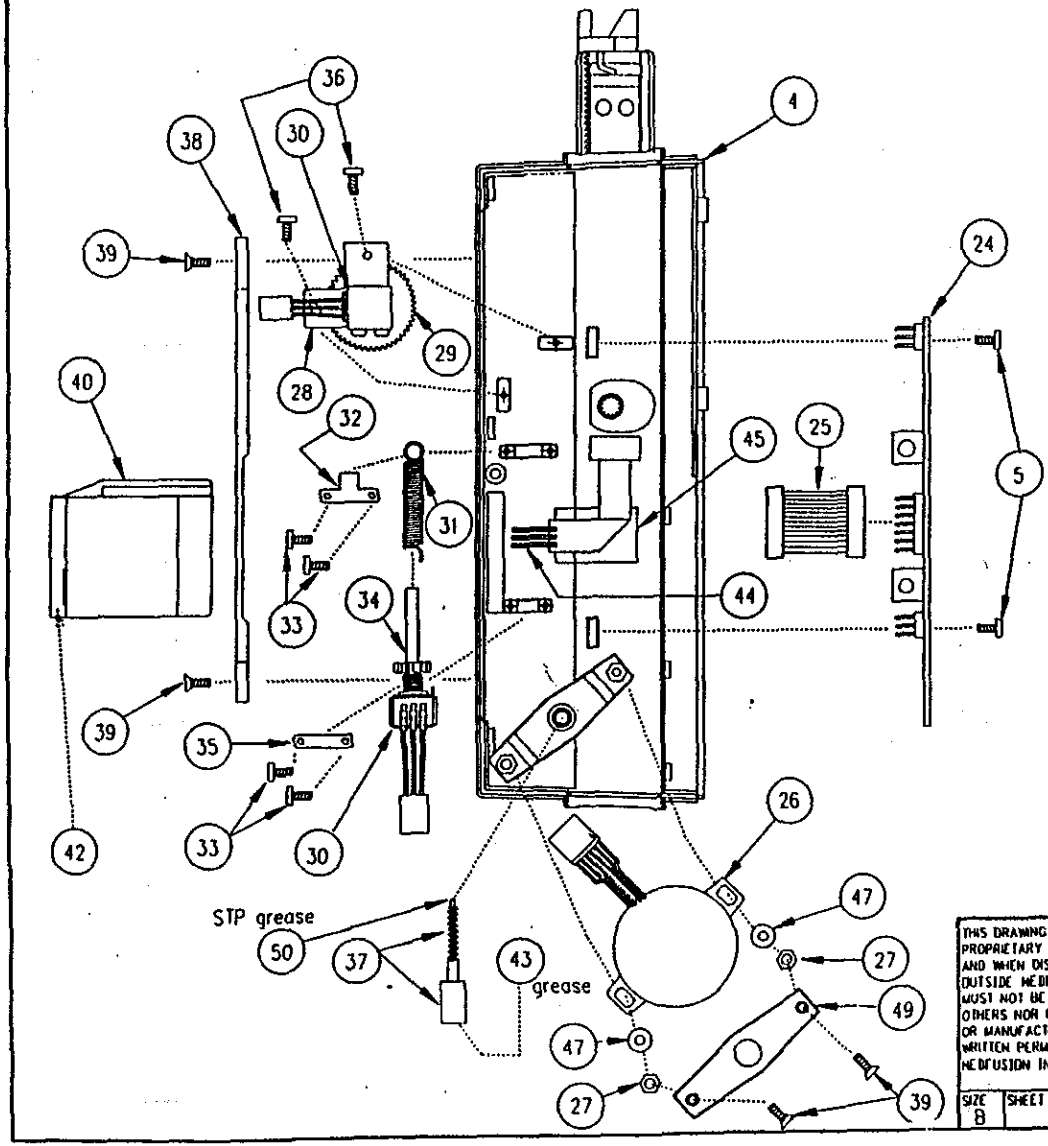
8. Attach the rubber boot (21) with tape (45) 1 inch long to the upper slide assembly.

THIS DRAWING CONTAINS PROPRIETARY INFORMATION AND WHEN DISTRIBUTED OUTSIDE MEDFUSION INC. MUST NOT BE DISCLOSED TO OTHERS NOR USED FOR SALE OR MANUFACTURE WITHOUT WRITTEN PERMISSION FROM MEDFUSION INC.

DWN	D. AMMANN	1-5-90
ENGR.	J. STEMPELE	1-5-90
CHK	D. AMMANN	1-5-90
PROD	B. KRATOFIL	1-5-90
APVD	R. BOOTH	1-5-90

MEDFUSION INC.

DIMENSIONS ARE IN INCHES — TOLERANCES UNLESS OTHERWISE NOTED
DEC — ANGLE
FINISH N/A — MATERIAL N/A
TITLE SLIDE HOUSING S/A
SIZE — SHEET 1 OF 2 — SCALE NONE
PRODUCT REFERENCE 2001 — PART NO. 1-68-2 0-5 — REV A



ASSEMBLY INSTRUCTIONS:

* SAFETY GLASSES REQUIRED

NOTE: All 2-56 screws are to be torqued 10 in/oz.
All 4-40 screws are to be torqued 16 in/oz.

1. Take clamp gear (34) and slip onto potentiometer shaft (30). Slide torsion spring (31) over gear shaft and engage open loop of torsion spring in slot of clamp gear.

   Place all of above assembly into both half-round recesses of slide housing (4) with the pot. body toward motor side. Take pot. clamp (35) and two pan head screws (33) and secure around pot. neck, but do not tighten screws.

   Rotate clamp gear counter-clockwise with torsion spring as seen looking at closed loop spring end until it stops.

   While maintaining stop out, rotate potentiometer with gear and spring together until closed spring loop is parallel with mounting surface of slide housing. The pot's cable should point away from circuit board. Now tighten both screws of pot clamp.

   Take clear syringe clamp (40) and enter gear rack side through rubber seal and engage with clamp gear while maintaining stop out and push syringe clamp all the way.

* Using the winding tool, engage the closed loop end and rotate the spring just past one full turn counter-clockwise until the loop is again parallel with the mounting surface. Secure the closed loop by placing the spring-end-clamp (32) through the loop and tighten with two pan head screws (33).

   Now loosen the pan head screws on the potentiometer and rotate the pot counter-clockwise about 20° to prevent the clear syringe clamp from disengaging with the gear. Final potentiometer position will be done later at calibration.

2. Attach the position pot holder (28) to a pot sub-assembly (30) with hardware supplied with pot. Push the position gear (29) onto the pot. Be sure the hub on the gear is towards the pot. Rotate the gear to the full counter clockwise position. Slide plunger/track to empty position. Reset the gear 5 teeth, then install the pot assembly to the slide bottom with two screws (36). Ensure clearance between the gears.

*3. Solder the three wires (44) to the force cable, then to the auxiliary PCB. Attach the PCB assembly (24) to the slide bottom with screws (5). Plug in both pots to the PCB.

4. Place worm gear into housing assembly.

5. Add grease (43) to coupling. Attach the worm/coupling to motor and secure it with the two 3/16 hex female standoffs (27) and two flat washers (47). Be sure motor is aligned with bracket and tighten securely.

6. Secure motor with motor mount back (49) and two pan head screws (5).

7. Snap slide door (38) into slide housing and secure with two screws (39).

8. Connect ribbon cable (25) to PC board.

THIS DRAWING CONTAINS PROPRIETARY INFORMATION AND WHEN DISTRIBUTED OUTSIDE MEDFUSION INC. MUST NOT BE DISCLOSED TO OTHERS NOR USED FOR SALE OR MANUFACTURE WITHOUT WRITTEN PERMISSION FROM MEDFUSION INC.

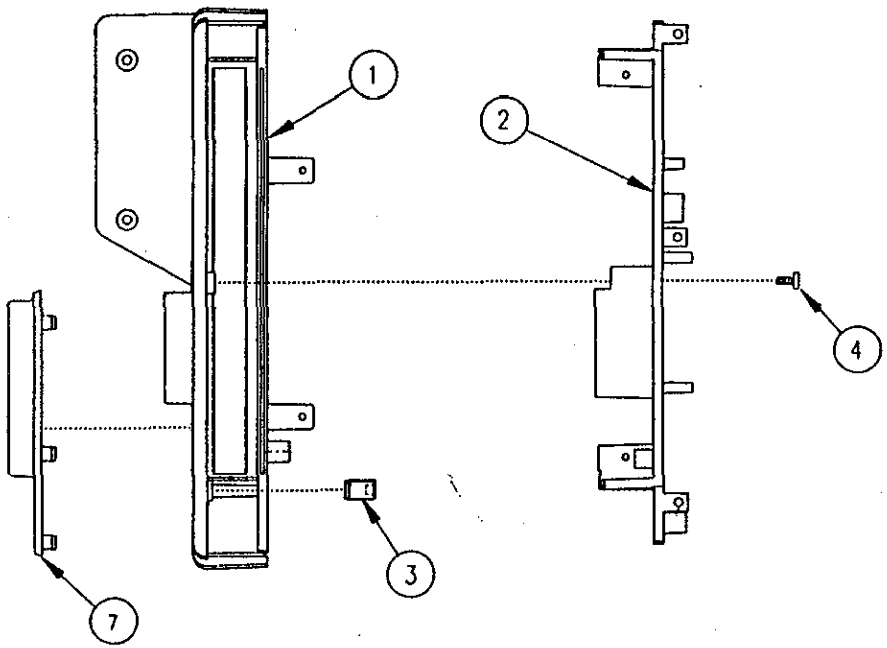
DWN.	D. AMMANN	1-5-90
ENGR.	J. STEMPFLE	1-5-90
CHK	D. AMMANN	1-5-90
PROD	B. KRATOFIL	1-5-90
APVD	R. BOOTH	1-5-90

SIZE B | SHEET 2 OF 2 | SCALE NONE

MEDFUSION INC.

DIMENSIONS ARE IN INCHES | TOLERANCES UNLESS OTHERWISE NOTED
DEC | ANGLE
FINISH N/A | MATERIAL N/A
TITLE SLIDE HOUSING S/A
PRODUCT REFERENCE 2001 | PART NO. 1-68-20A02-0 5 | REV A

REV	REF	DESCRIPTION OF REVISION	APPROVED	DATE
1	90060101	REMOVED BALL BEARING	J.STEMPFLE R.BOOTH	6-5-90 6-6-90
A	91060302	SAFETY WARNING ADDED		6-14-91 6-14-91



8 SILICONE ADHESIVE

6 SOLVENT GLUE

ASSEMBLY INSTRUCTIONS:

SAFETY GLASSES REQUIRED

1. APPLY GLUE (6) BETWEEN THE PRONGS OF THE SYRINGE SADDLE (7) AND SNAP THE SYRINGE SADDLE INTO THE SLIDE TOP (1). GLUE (8) THE SIX PRONGS ON THE BACK SIDE.
2. PRESS THE THRUST BEARING INTO THE SLIDE TOP
3. GLUE (ITEM#6) ALL THE EDGES OF THE SLIDE BOTTOM THAT CONTACT THE SLIDE TOP. PRESS THE SLIDE BOTTOM INTO THE SLIDE TOP AND SECURE THE ASSEMBLY WITH THE PAN HEAD SCREW (4). CLAMP (WITH SOLVENT BONDING FIXTURE #0-66-20001-0-0) ASSEMBLY UNTIL DRY

THIS DRAWING CONTAINS PROPRIETARY INFORMATION AND WHEN DISTRIBUTED OUTSIDE MEDFUSION INC. MUST NOT BE DISCLOSED TO OTHERS NOR USED FOR SALE OR MANUFACTURE WITHOUT WRITTEN PERMISSION FROM MEDFUSION INC.

DWN.	D. AMMANN	1-5-90
ENGR.	J. STEMPFLE	1-5-90
CHK	D. AMMANN	1-5-90
PROD	B. KRATOFIL	1-5-90
APVD	R. BOOTH	1-5-90

MEDFUSION INC.

DIMENSIONS ARE IN INCHES
DEC
TOLERANCES UNLESS OTHERWISE NOTED
ANGLE

FINISH N/A

MATERIAL N/A

TITLE SLIDE S/A

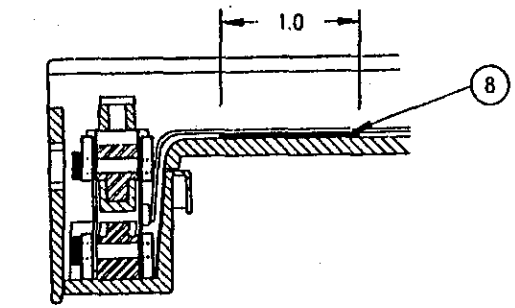
SIZE B | SHEET 1 OF 1 | SCALE NONE

PRODUCT REFERENCE 2001

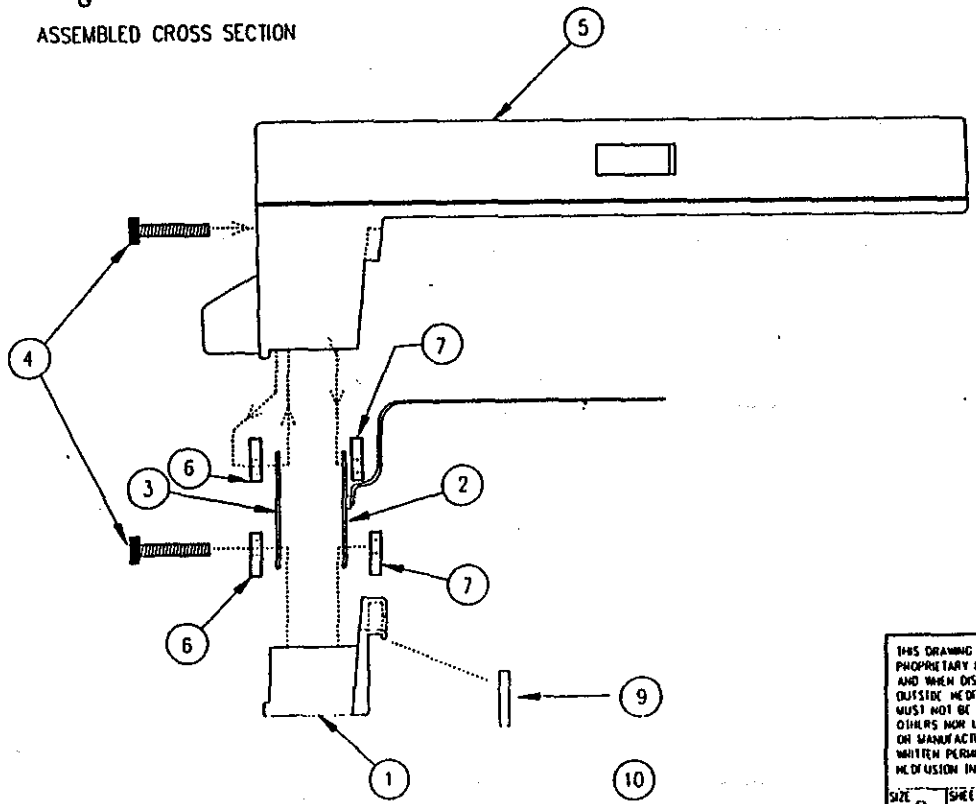
PART NO. 1-68-20A03-0-1

REV A

REV	DCN #	DESCRIPTION OF REVISION	APPROVED	DATE
1	90103101	ITEMS 9 & 10 WERE ADDED	R. BOOTH	11-1-90
			D.AMMANN	11-1-90
A	91060302	SAFETY WARNING ADDED		6-14-91
				6-14-91



ASSEMBLED CROSS SECTION



ASSEMBLY INSTRUCTIONS:

* SAFETY GLASSES REQUIRED

1. Insert transducer nut plate (7) (note orientation) into plunger holder (1).
2. Insert force sensor plate with cable (2) between transducer nut plate (7) (note cable orientation) and plunger holder (1).
3. Insert blank sensor plate (3) and screw plate (6) (note orientation) into plunger holder (1). Align (2) & (3) before tightening socket head screw (4). Torque to a screwdriver setting of 20 in/lb.
4. Place plunger holder assembly into track.
5. Insert transducer nut plate (7) (note orientation) into assembly. Do not press into the ribbon cable. Holding the nut plate with *one hand*, tilt the assembly upright and place the transducer screw plate (6) (note orientation)into position. Ensure alignment of all parts. *Secure remaining* socket head screw (4) into position.
6. Insert shims to center plunger holder. Tighten remaining socket head screw to 20 in/lbs.
7. Place about one inch of double sided tape (8) on inside of track (5).
8. Press on cable to secure to tape.
*9. Glue plunger retainer (9) to plunger holder (1) with glue (10).

THIS DRAWING CONTAINS PROPRIETARY INFORMATION AND WHEN DISTRIBUTED OUTSIDE MEDFUSION INC. MUST NOT BE DISCLOSED TO OTHERS NOR USED FOR SALE OR MANUFACTURE WITHOUT WRITTEN PERMISSION FROM MEDFUSION INC.

DWN	D.AMMANN	12.11.89
ENGR	L.GARCIA	12.12.89
CHK	D.AMMANN	1.05.89
PROD	B.KRAIOFIL	1.05.90
APVD	R.BOOTH	1.05.90
DCN #	NA	SCALE NONE

MEDFUSION INC.

DIMENSIONS ARE IN INCHES — TOLERANCES UNLESS OTHERWISE NOTED
FINISH NA — ANGLE NA
MATERIAL NA

TITLE PLUNGER HOLDER/TRACK S/A

SIZE B — SHEET 1 OF 1 — PRODUCT REFERENCE 2001 — PART NO 1-68-20A04-0-1 — REV A

APPENDIX B. SCHEMATIC DIAGRAMS

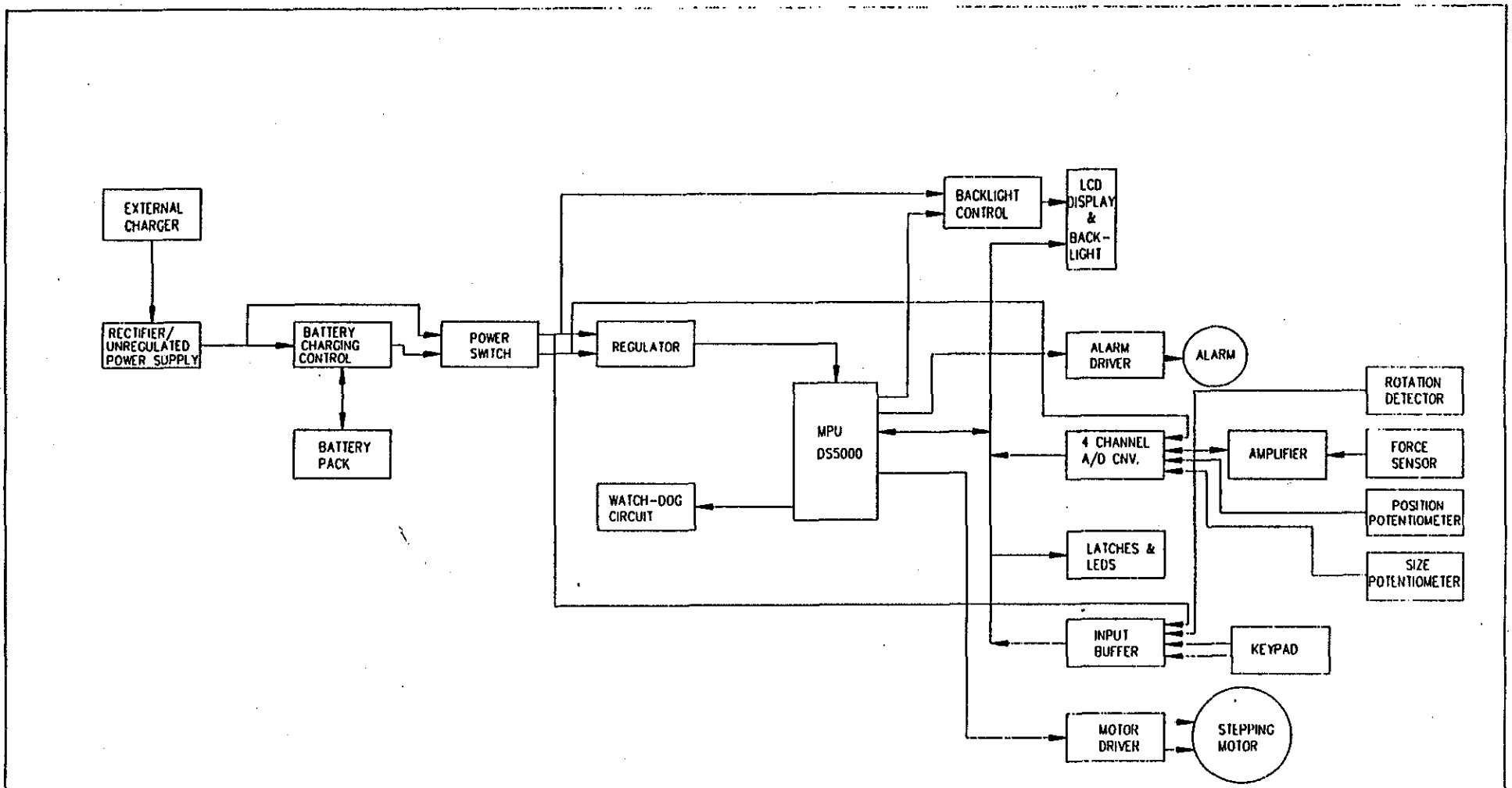
B.1 System Block Diagram

B.2 Schematic, Main Board

B.3 Schematic, Auxiliary Board

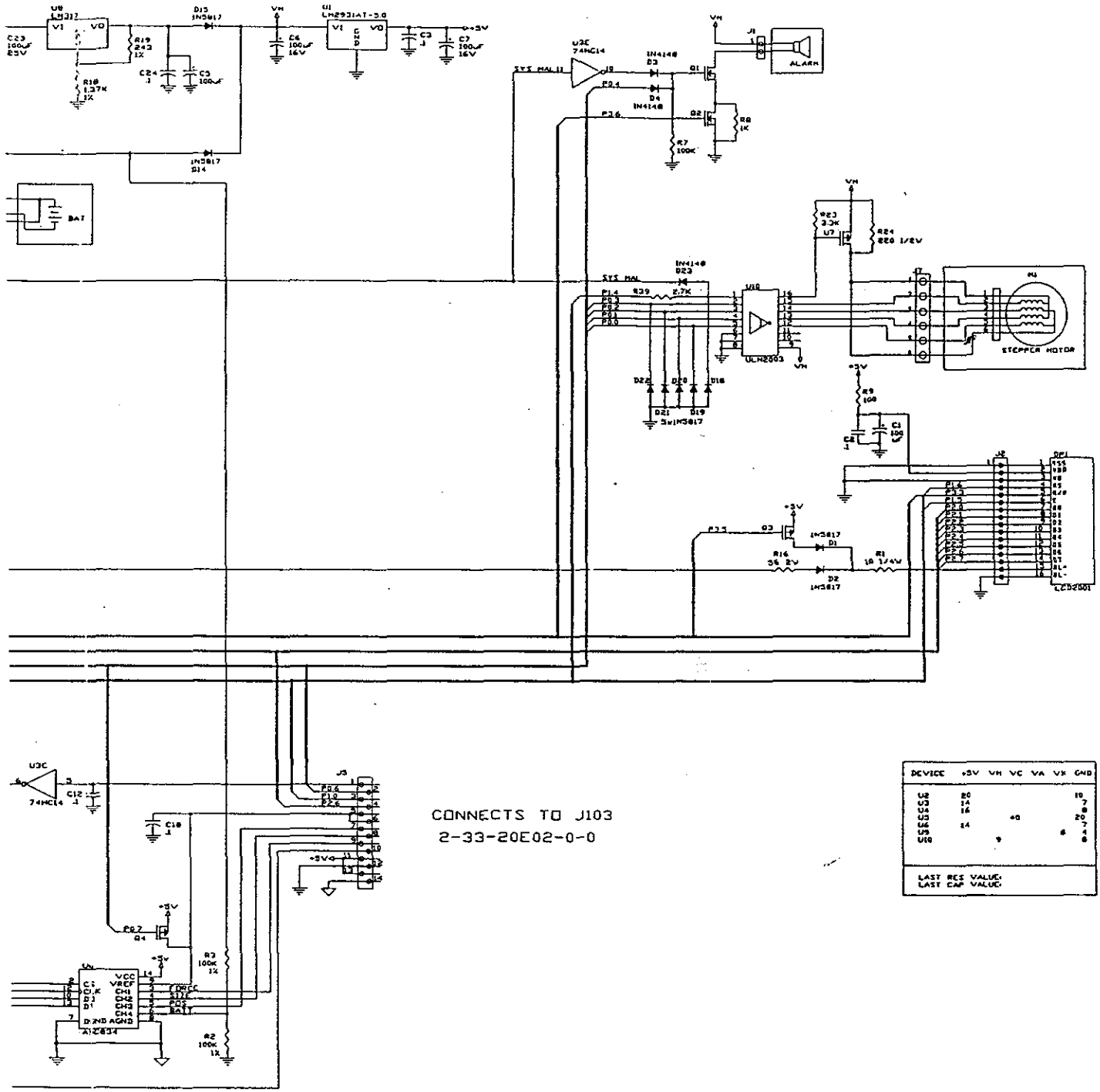
B.4 Main Board S/A

B.5 Auxiliary Board S/A



SYSTEM BLOCK DIAGRAM, 2001/2010

REV	REFERENCE	DESCRIPTION OF REVISION	APPROVED	DATE
0 1	89120701	MOVED C23 AND PALATIZED ARTWORK	L. GARCIA	1-03-90
			R. BOOTH	1-03-90
1 2	90052101	CHANGED C33 TO C13 TO MATCH PCB		7-12-90
				7-13-



CONNECTS TO J103
2-33-20E02-0-0

DEVICE	+5V	VH	VC	VA	VX	GND
U8	20					10
U3	14					7
U5	16					8
U6			+8			20
U7	16					7
U10					6	4
		9				8

LAST RES VALUE:
LAST CAP VALUE:

THIS DRAWING CONTAINS PROPRIETARY INFORMATION AND WHICH DISTRIBUTED OUTSIDE MEDFUSION SYSTEMS MUST NOT BE DISCLOSED TO OTHERS NOR USED FOR SALE OR MANUFACTURE WITHOUT WRITTEN PERMISSION FROM MEDFUSION SYSTEMS INC.

DWN.	LUIS GARCIA-VERONA	JAN 3 1990
ENGR.	LUIS GARCIA-VERONA	JAN 3 1990
CHK.	DAVE ARMANN	JAN 3 1990
PROD.	BRIAN KRATOFL	JAN 3 1990
APVD.	RUFFIN BOOTH	JAN 3 1990

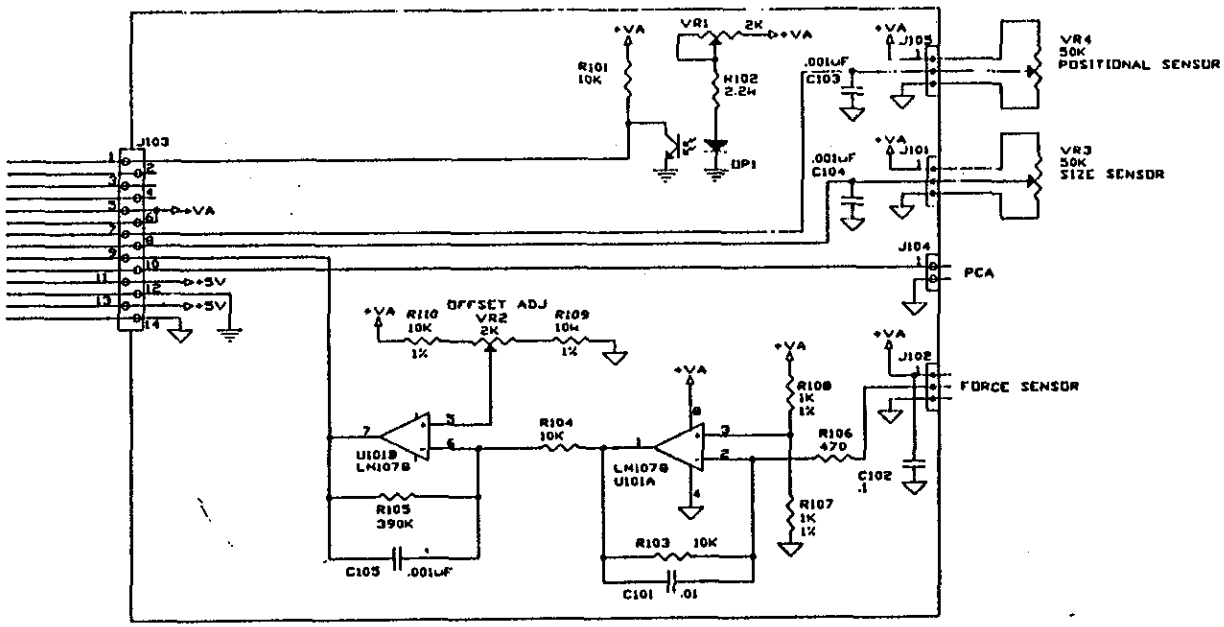
MEDFUSION INC.

DIMENSIONS ARE IN: DEC N/A, FINISH N/A
TOLERANCES UNLESS OTHERWISE NOTED: ANGLE N/A, MATERIAL N/A
TITLE: MAIN PCB

SIZE	SHEET	SCALE	PRODUCT REFERENCE	PART NO.	REV
D	1 OF 1	NONE	PUMP 2001	2-33-20E01-0-2	0

REV	REFERENCE	DESCRIPTION OF REVISION	APPROVED	DATE
0 1	90052101	Added C103, C104, C105	L Garcia V V	7-12-90 7-12-90

CONNECTS TO J5
2-33-20E01-0-0



THIS DRAWING CONTAINS PROPRIETARY INFORMATION AND WHEN DISTRIBUTED OUTSIDE MEDFUSION SYSTEMS MUST NOT BE DISCLOSED TO OTHERS NOR USED FOR SALE OR MANUFACTURE WITHOUT WRITTEN PERMISSION FROM MEDFUSION SYSTEMS INC.

DWN.	LUIS GARCIA-VERONA	JAN 5, 1990
ENGR.	LUIS GARCIA-VERONA	JAN 5, 1990
CHK.	DAVE AHMANN	JAN 5, 1990
PROD.	BRIAN KRATOFIL	JAN 5, 1990
APVD.	RUFFIN BUOTH	JAN 5, 1990

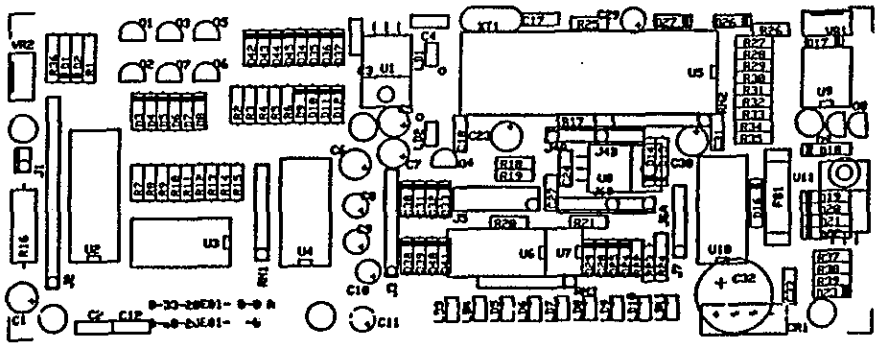
MEDFUSION INC.

DIMENSIONS ARE IN DEC N/A
TOLERANCES UNLESS OTHERWISE NOTED ANGLE N/A
FINISH N/A
MATERIAL N/A
TITLE AUX PCB

SIZE	SHEET	SCALE	PRODUCT REFERENCE	PART NO.	REV
B	1 OF 1	NONE	PUMP 2001	2-33-20E02-0-1	0

REV	REF	DESCRIPTION OF REVISION	APPROVED	DATE

PART NO. 1-68-20E01-0-0 REV 0



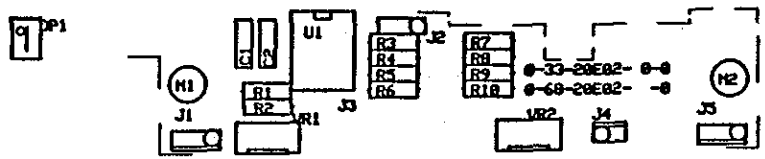
THIS DRAWING CONTAINS PROPRIETARY INFORMATION AND WHEN DISTRIBUTED OUTSIDE MEDFUSION INC. MUST NOT BE DISCLOSED TO OTHERS NOR USED FOR SALE OR MANUFACTURE WITHOUT WRITTEN PERMISSION FROM MEDFUSION INC.	DWN. L. GARCIA-VERONA 1.5.90 ENGR. 1-5-90 CHK 1-5-90 PROD 1-5-90 APVD 1/5/90	MEDFUSION INC.	
		DIMENSIONS ARE IN INCHES DEC N/A	TOLERANCES UNLESS OTHERWISE NOTED ANGLE N/A
		FINISH N/A	MATERIAL N/A
		TITLE 2001 MAIN PCB S/A	
SIZE B SHEET 1 OF 1	SCALE NONE	PRODUCT REFERENCE PUMP 2001	PART NO. 1-68-20E01-0-0 REV 0

1005174

068-2E18STO

REV	REF	DESCRIPTION OF REVISION	APPROVED	DATE

PART NO. 1-68-20E02-0-0 REV 0



THIS DRAWING CONTAINS PROPRIETARY INFORMATION AND WHEN DISTRIBUTED OUTSIDE MEDFUSION INC. MUST NOT BE DISCLOSED TO OTHERS NOR USED FOR SALE OR MANUFACTURE WITHOUT WRITTEN PERMISSION FROM MEDFUSION INC.

DWN. L. GARCIA-VERONA	1.5.90	MEDFUSION INC.
ENGR.	1-5-90	
CHK	1-5-90	DIMENSIONS ARE IN INCHES — TOLERANCES UNLESS OTHERWISE NOTED
PROD	1-5-90	DEC N/A — ANGLE N/A
APVD	1/5/90	FINISH N/A — MATERIAL N/A
SCALE NONE		TITLE 2001 AUX PCB S/A
SIZE B — SHEET 1 OF 1		PRODUCT REFERENCE PUMP 2001 — PART NO 1-68-20E02-0-0 — REV 0

APPENDIX C. MICRO-CONTROLLER I/O PORT DEFINITIONS

Port 0:

P0.0-P0.3:	(output) stepper motor waveform
P0.4:	(output) alarm ON(1) / OFF(0)
P0.5-P0.6:	not used
P0.7:	(output) A/D REF power(VA)* ON(0) / OFF(1)

Port 1:

P1.0-P1.3:	input from Multiplexer
	: Keypad input; if P3.7=1, P1.6=0, P2.7=1
	: P1.0-ROT, P1.1-AC; if P3.7=1, P1.6=0, P2.7=0
P1.3:	input from A/D if P3.7=0, P1.6=1, P0.7=0
P1.4:	output, Motor power High (1), Low (0)
P1.5:	output, LCD control E
P1.6:	output, LCD control RS or Mutiplexer OE* (0-enabled)
P1.7:	output, LED latch clock

Port 2:

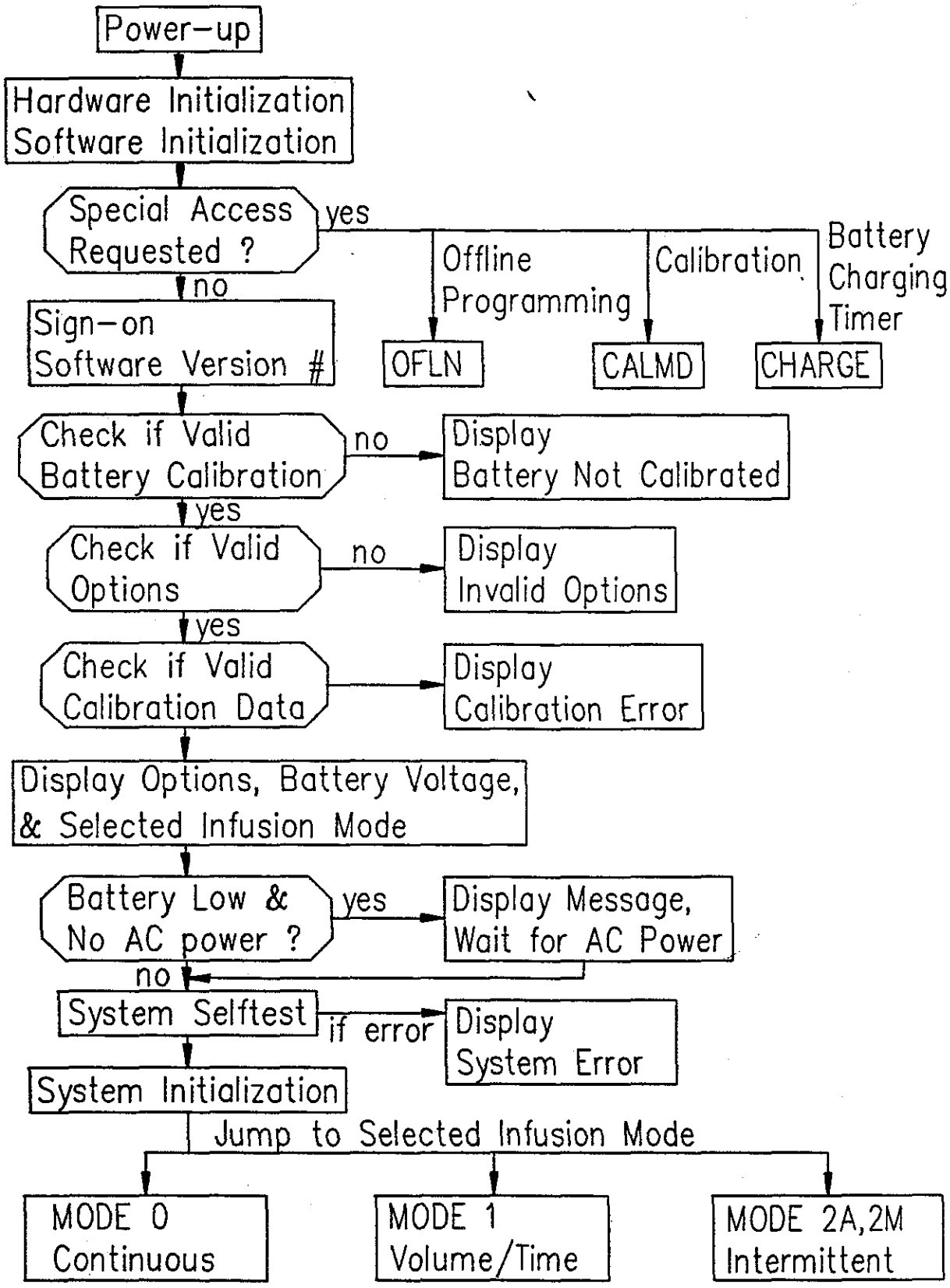
P2.0-P2.7:	8-bit data bus to LCD display and LED latch
P2.0-P2.3:	output scanning signals for the keyboard
P2.4:	output, A/D CLK
P2.5:	output, A/D DI (data input)
P2.7:	output, select one set of inputs from multiplexer.

Port 3:

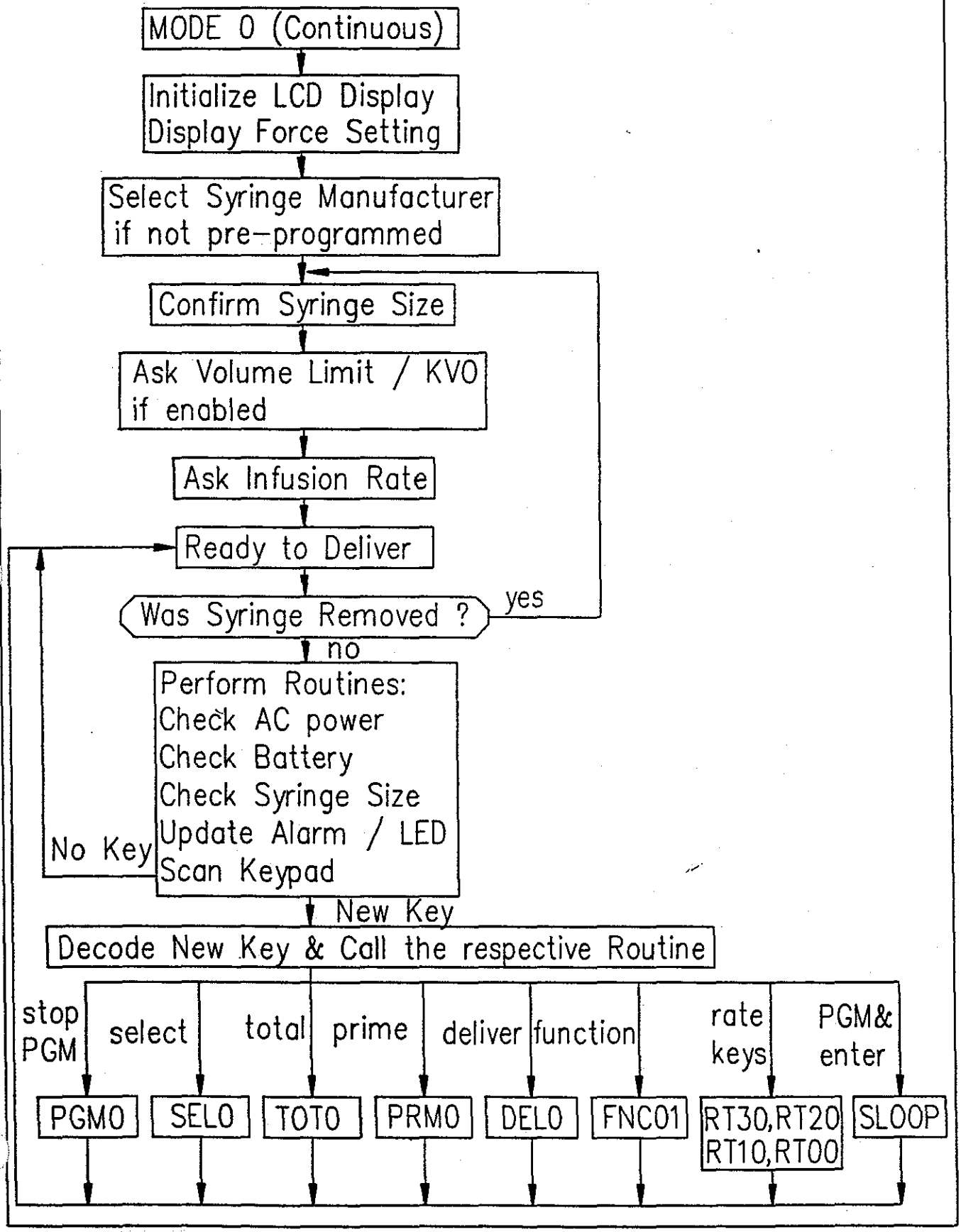
P3.0:	output, send pulses to the watchdog circuit
P3.1-P3.2:	reserved for serial communication
P3.3:	output, control LCD display Read(1) / Write(0)
P3.4:	output, Volume Limit LED ON(1) / OFF(0)
P3.5:	output, LCD backlight* ON (0) / OFF(1)
P3.6:	output, Alarm Volume Loud(1) / Soft(0)
P3.7:	output, CE* control for A/D (0-enabled)

APPENDIX D.1 SOFTWARE FLOW CHARTS (2001)

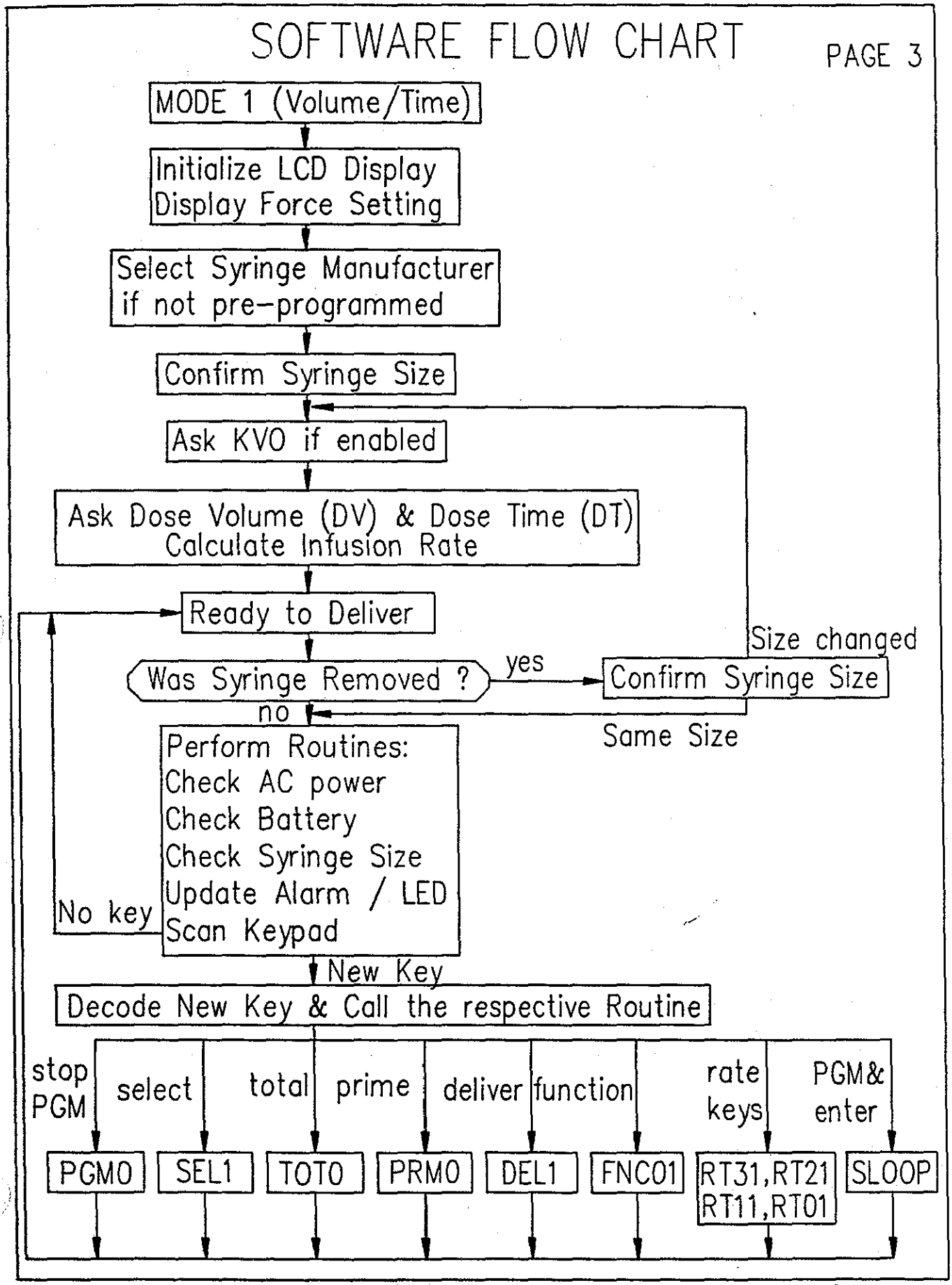
SOFTWARE FLOW CHART



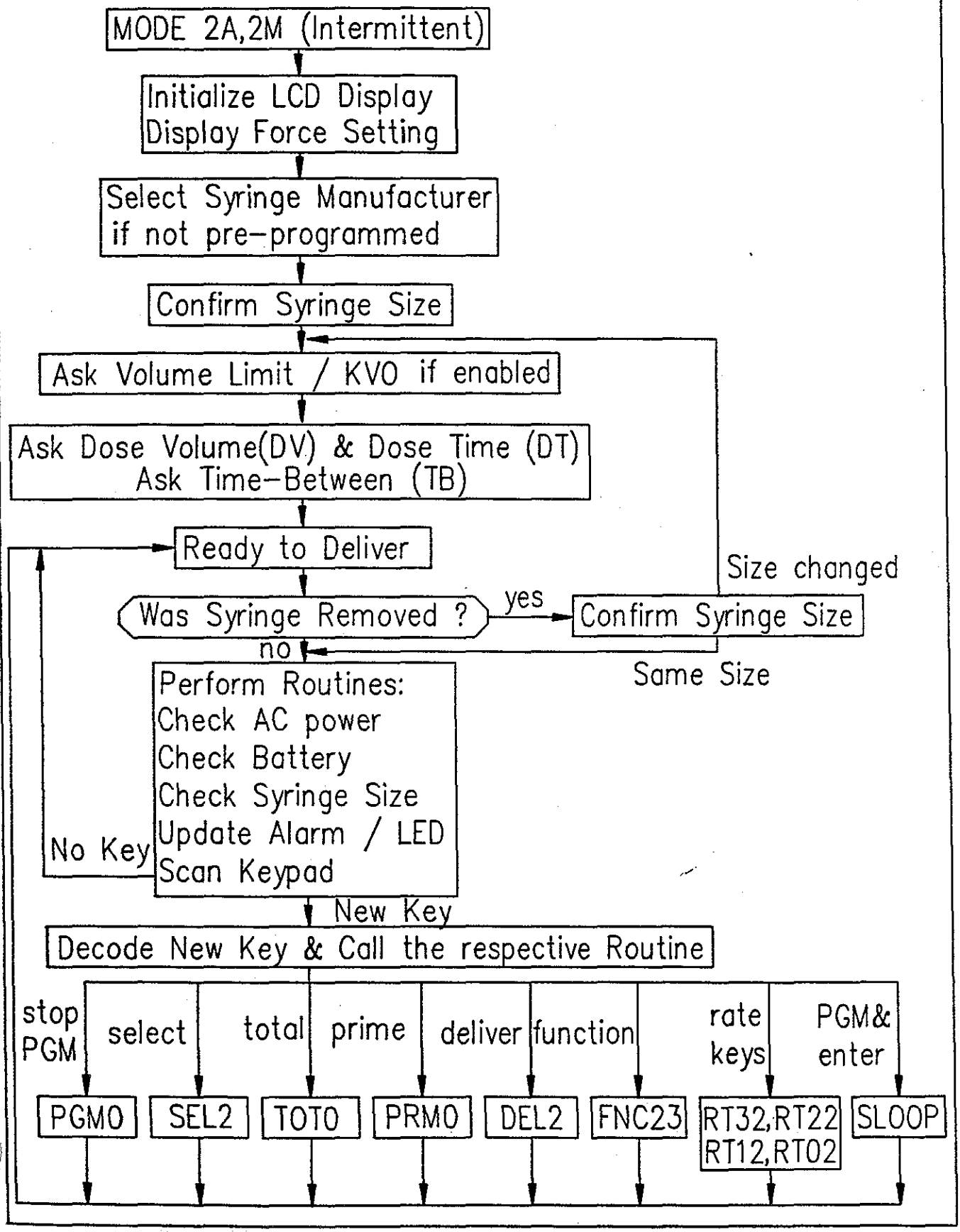
SOFTWARE FLOW CHART



SOFTWARE FLOW CHART

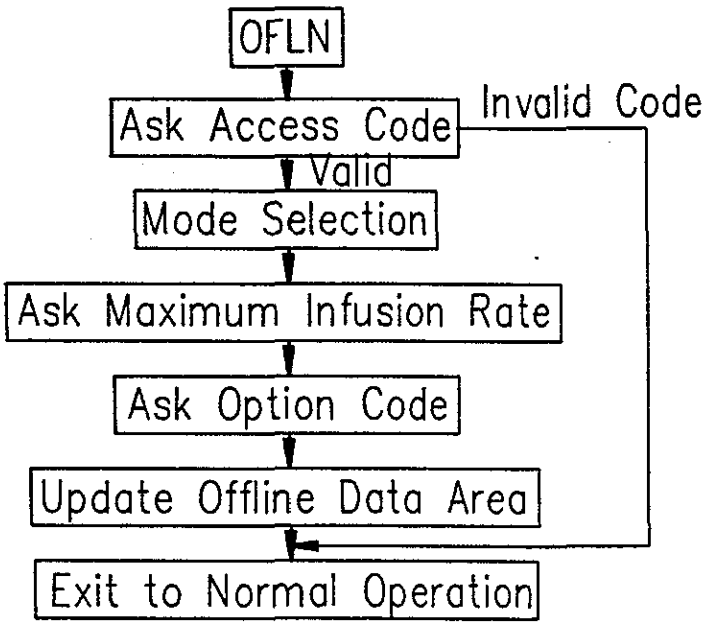


SOFTWARE FLOW CHART

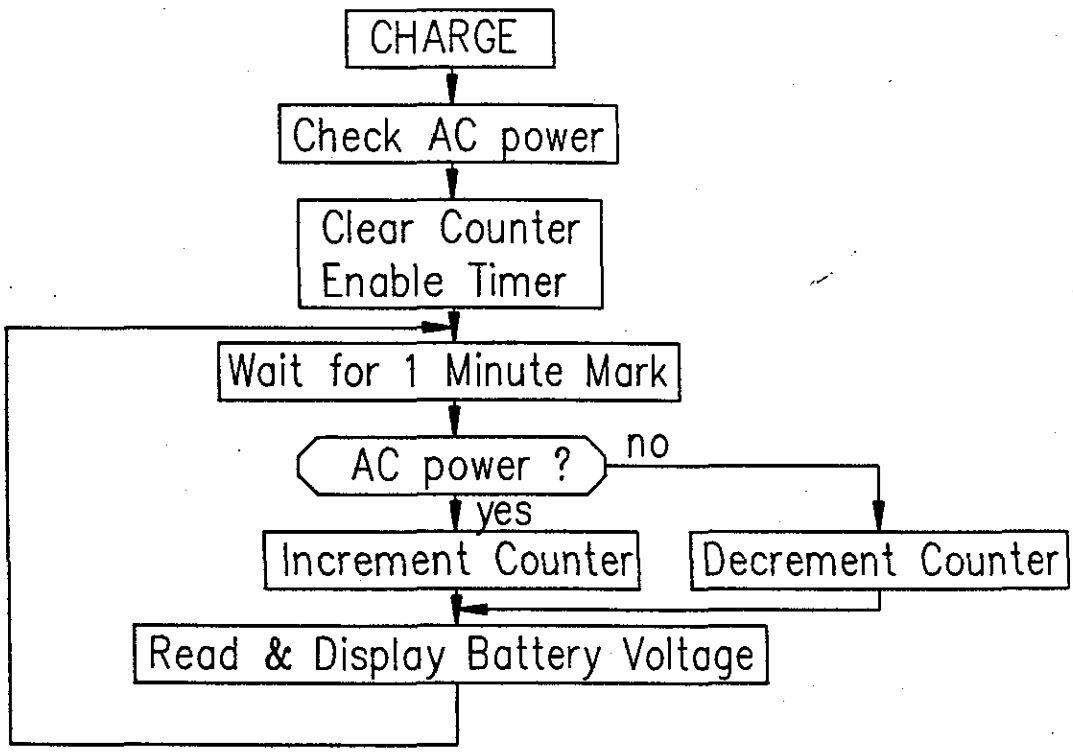


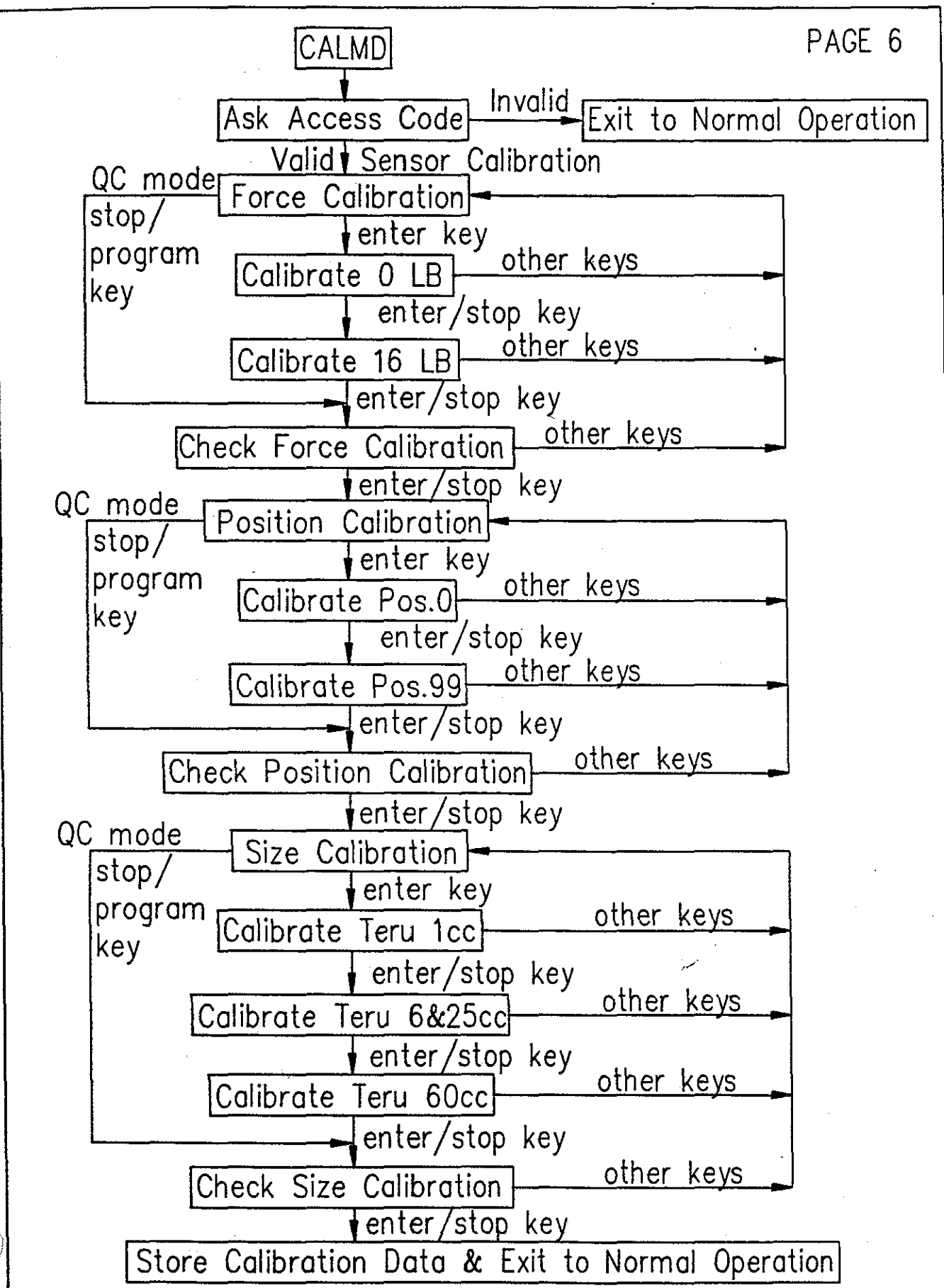
SOFTWARE FLOW CHART

OFFLINE PROGRAMMING



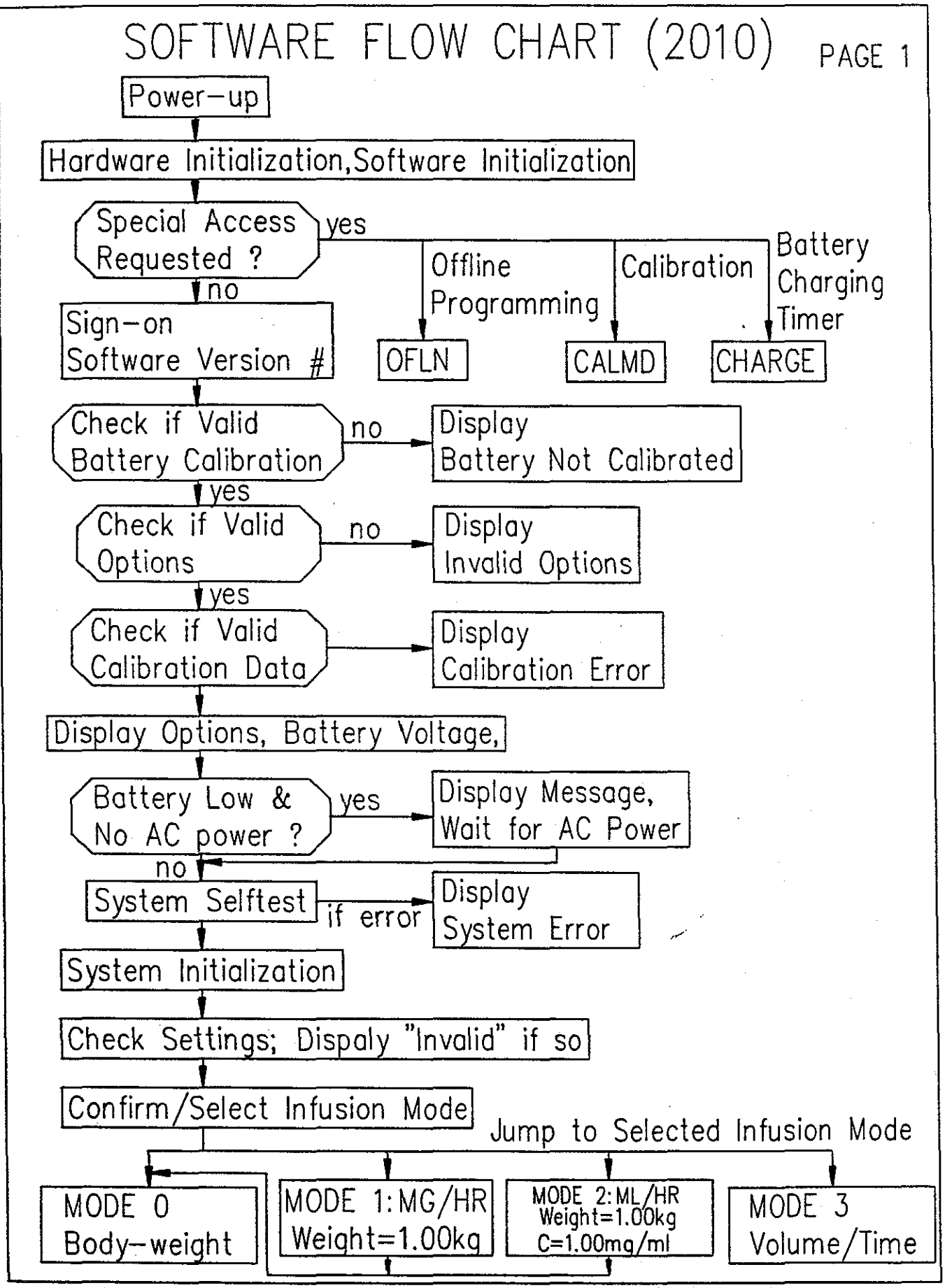
BATTERY CHARGING TIMER



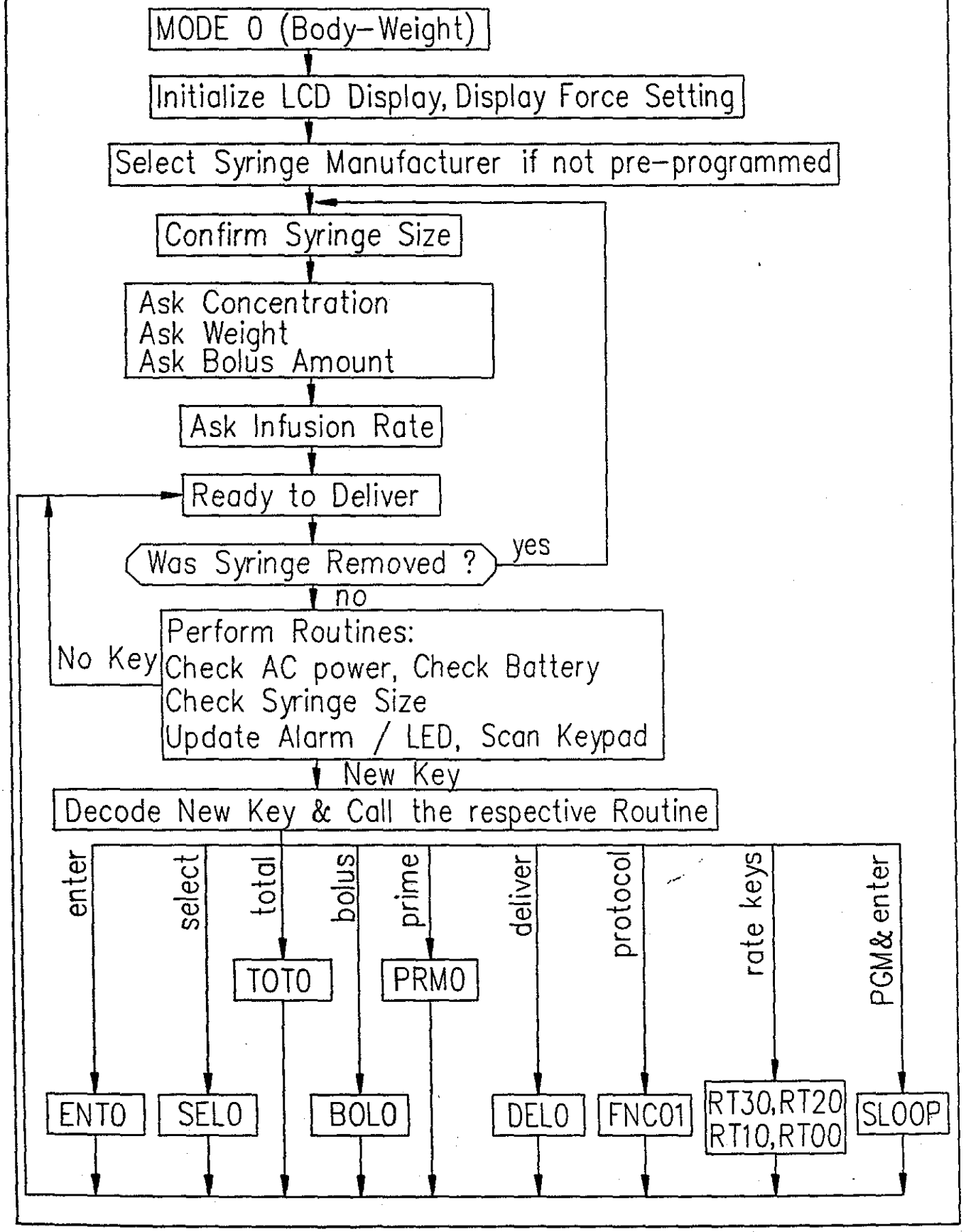

CALMD
Ask Access Code
Invalid
Exit to Normal Operation
Valid
Sensor Calibration
QC mode
stop/
program
key
Force Calibration
enter key
Calibrate 0 LB
other keys
enter/stop key
Calibrate 16 LB
other keys
enter/stop key
Check Force Calibration
other keys
enter/stop key
QC mode
stop/
program
key
Position Calibration
enter key
Calibrate Pos.0
other keys
enter/stop key
Calibrate Pos.99
other keys
enter/stop key
Check Position Calibration
other keys
enter/stop key
QC mode
stop/
program
key
Size Calibration
enter key
Calibrate Teru 1cc
other keys
enter/stop key
Calibrate Teru 6&25cc
other keys
enter/stop key
Calibrate Teru 60cc
other keys
enter/stop key
Check Size Calibration
other keys
enter/stop key
Store Calibration Data & Exit to Normal Operation

APPENDIX D.2 SOFTWARE FLOW CHARTS (2010)

SOFTWARE FLOW CHART (2010)



SOFTWARE FLOW CHART (2010)



APPENDIX E. QC Test Procedure

(System Performance Tests)

TITLE: Q.C. Final Test Procedure, Model 2001	PAGE 1 OF 6
SPECIFICATION: 4-72-20001-0-5	REVISION: 5

1.0 PURPOSE:

1.1 To establish a detailed test procedure to demonstrate that the Model 2001 meets inspection specifications.

2.0 SCOPE:

2.1 The Q.A. Inspector is responsible for the inspection, acceptance/rejection and notifying accounting.

2.2 The electronics technician will test the pumps prior to sampling by Q.C.

2.3 The Director of Quality Assurance (or designate) is responsible for assuring compliance with this procedure.

3.0 RELATED PROCEDURES AND DOCUMENTS:

3.1 Form P-72-20001-0-X, Q.C. Test Report Form (X = Latest revision)

3.2 Associated Assembly Specifications

3.3 Model 2001 Operator's Manual

3.4 Form P-72-20002-0-X, Batch Functional Test

3.5 Form P-72-20003-0-X, P-72-20004-0-X or P-72-20005-G-X Syringe Recognition Test

3.6 GMP Regulations

3.7 MIL-STD-105D

3.8 Syringe Infusion Pump Flow Test Procedure, 4-72-FLOW1-0-X

4.0 ASSOCIATED MATERIALS:

4.1 Hand tools

4.2 AC power source

4.3 Force transducer test gauge

5.0 PROCEDURE:

5.1 Pumps are delivered to Q.C. by production in batches. Several batches may make up a work order. Record on inspection forms: P-72-20001-0-X and P-72-20002-0-X (where appropriate). See 4-61-20010-G-X for German Screen Translations (if applicable).

5.1.1 Identify pump model/serial number.

5.1.2 Record the work order on the inspection form.

5.1.3 The Q.C. Inspector will test per forms P-72-20001-0-X and P-72-20002-0-X.

5.2 Inspection procedure

5.2.1 Visual Inspection

5.2.1.1 Inspect for presence of S/N-UL label and Charger label on pump's rear panel, checking for legibility and record serial number on the Inspection Form.

5.2.1.2 Rubber bumpers are attached to the bottom (4 each).

5.2.1.3 Check for front panel's printing and legibility.

5.2.1.4 On/off switch is oriented with the "1" towards the slide.

5.2.1.5 Check overall cosmetic appearance. No finger print on LCD window.

5.2.1.6 Turn unit on all sides and check for any loose parts both internal and external.

5.2.2 Operational Checks: Battery Mode

5.2.2.1 Check syringe slide operation. With clutch disengaged, carriage must slide freely along it's full travel with no appreciable friction or binding. Clutch should freely disengage and spring back into engagement.

5.2.2.1.1 Syringe Plunger Retainer should be firmly attached to Syringe Driver.

5.2.2.2 Check for proper lift and function of the syringe clamp. For German Pump, use German syringes. Clamp must lock onto syringe tabs.

5.2.2.3 With unit unplugged from AC power, turn the power switch on. After checks, unit should be in program mode with audio alarm and "battery in use" (German: "BATT. Betrieb") light illuminated. Record on the top of the form the software version, the battery voltage, the alarm delay and the number of the options. Use overlay and manual with German displays added for German version.

Observe for:

5.2.2.3.1 Proper software revision
5.2.2.3.2 Proper power-up system check
5.2.2.3.3 Alarms sound quality and volume
5.2.2.3.4 LED's function
5.2.2.3.5 LCD display contrast

5.2.2.4 Programming - Select mode (continuous, volume/time, intermittent-auto or intermittent-manual, if programmed), syringe manufacturer, load syringe, volume limit and Keep Vein Open (KVO) (if applicable), rate, and cancel audio alarm. Verify operation of all keys used during this sequence. The pumps may be preprogrammed to exclude certain options. Vary the modes, manufactures and rates for different pumps.

5.2.2.5 Push and hold "prime" key until continuous audio alarm sounds (about 16 seconds). (Display should indicate PRIME VOL = XX.XX ML.) Verify visually syringe cradle movement.

5.2.2.6 Press "deliver" key. Unit should begin moving the syringe cradle, and incrementing the Running Volume display and the Total Volume delivered display.

5.2.2.7 Test the occlusion alarm as follows:

5.2.2.7.1 While in the deliver mode apply hand pressure to the end of the slide that meets the syringe

plunger to activate the occlusion alarm. The pressure required to activate the alarm will vary with the syringe size, less is needed for the small syringe sizes and more is needed for the larger sizes.

5.2.2.8 Resume the deliver mode, run cradle through "near empty" to "empty" alarms and verify alarm function.

5.2.2.9 After empty alarm, pressing "reset total volume" button should change the "Total Volume" display to 0.00.

5.2.2.10 Pressing the "backlight" button, or any key in the DC mode, should cause the LCD backlight to illuminate. You may need to turn off the room lights to check this.

5.2.2.11 Check motor for noise using a B-D 60cc at 60 ml/hr for 1 minute. Reject pump if excessive noise is observed.

5.2.3 Operational Checks: AC Mode

5.2.3.1 Plug unit in AC receptacle, and turn power switch off, then on. Unit should go through power up sequence as in 5.2.2.3, except that "battery in use" LED should be off, and "battery charging" LED should be on.

5.2.3.2 Verify unit programs properly, as in 5.2.2.4. Place in deliver mode.

5.2.3.3 Verify backlight to illuminate in the AC mode. You may need to turn off the room lights to check this.

5.2.3.4 Turn the AC power off, leaving the unit's power switch on. No interruption in function should occur, but the "battery in use" LED should illuminate.

5.2.3.5 Turn the unit's power switch off. Plug unit in AC receptacle, depress and hold "stop/program" and "deliver" keys simultaneously while turning the units power switch to on. Unit should display "BATTERY TIME=00.00". After one minute the LCD will display "BATT.V= X.X".

5.2.3.6 The inspector performing the testing signs and dates the form.

5.2.4 Transducer Calibration Check

5.2.4.1 Press stop/program and select key at the same time, turn pump on, hold for approximately one second and release. Lock = 000.0 will appear on the display. Key in 100.0 onto the display. Press enter. Access complete. Display will show "Force (lb) 00.XX=XX".

5.2.4.2 Test the occlusion pressure using the 2001 force gauge. Place gauge on the pump, and set gauge to the values stated on the "Q.C. Final Test Report, Model 2001". The 2001 Pump display should read within the stated tolerances.

5.2.4.2.1 The tolerances are as follows:
1.5±.5,
8.0±.75,
15.0±1.5.

5.2.5 Position Sensor Test (This test should be done with the clutch disengaged.)

5.2.5.1 Press the stop/program key once. Pos. (inch) appears on display. For the first readings, move track so that 0.000 is shown on the display. Record this number and its corresponding HEX number. Move track so that 4.836 ± .005 is shown on the display. Record this number and its corresponding HEX #. For the second readings, move the track to the lowest point possible. Record this # and its corresponding HEX #. Move the track to the highest point possible. Record this # and its corresponding HEX #. Verify that the lowest point HEX # is equal to or less than the 0 reading HEX # by one HEX digit only. Verify that the highest point HEX # is equal to or greater than the 4.836 reading HEX # by one HEX digit only.

5.2.5.2 The inspector performing the testing signs and dates the form.

5.2.6 Syringe Recognition Test

5.2.6.1 Press the stop/program key once again. Size (inch) will appear on the display. Insert syringes listed on "Syringe Recognition Report, P-72-20003-0-X or P-72-20004-0-X, if applicable. Read number on display between high and low for each syringe.

5.2.6.2 The inspector performing the testing signs and dates the form.

5.2.7 Flow Test

5.2.7.1 Perform flow testing as required on form P-72-20002-0-X or P-72-20001-0-X. Use any size syringe in the volume/time mode. Test should last 20 minutes mimimum using more than 70% of the pipette. Refer to Flow Test Procedure 4-72-FLOW1-0-X.

5.2.7.2 The inspector performing the testing signs and dates the form.

5.2.8 Final Check

5.2.8.1 Check for presence of screw covers over 4 screws. Two in line with the brass pole mount inserts and two screws closest to the face plates. Check for tamper evident label on screw on the back bottom center.

5.3 Inspection Forms

5.3.1 Fill in the Inspection Form, P-72-20001-0-X for Model 2001, for all test categories. Note any improper function in the reject column and comments section. Any reject must be separated and handled in accordance with the Q.A. Manager's instructions. The form must be signed and dated.

5.3.2 Form number P-72-20002-0-X, Batch Functional Test - Model 2001, should also be completed for each batch of pumps delivered to Q.C. Instructions are on the form.

Q.C. Final Test Report, Model 2001
Preprogrammed Settings:

(See Procedure 4-72-20001-0-X)

S/N_____
Software Version_____
Work Order:_____

_____ _____ _____ _____
Alarm Vol. Alarm Delay Batt. V. Options

		Accept	Reject
5.2.1	VISUAL:		
5.2.1.1	S/N-UL Label and Charger Label attached	_____	_____
5.2.1.2	Rubber bumpers attached (4)	_____	_____
5.2.1.3	Face plate printing and I.D.	_____	_____
5.2.1.4	On/off switch properly oriented	_____	_____
5.2.1.5	Overall appearance	_____	_____
5.2.1.6	Loose parts - internal and external	_____	_____
5.2.2	OPERATIONAL CHECKS:		
5.2.2.1	Syringe slide function	_____	_____
5.2.2.1.1	Syringe plunger retainer attached	_____	_____
5.2.2.2	Syringe clamp function	_____	_____
5.2.2.3	Power switch function	_____	_____
5.2.2.3.1	Proper software revision	_____	_____
5.2.2.3.2	Proper power up system check	_____	_____
5.2.2.3.3	Alarms sound quality and volume	_____	_____
5.2.2.3.4	LED's function	_____	_____
5.2.2.3.5	LCD display contrast	_____	_____
5.2.2.4	Programmable	_____	_____
5.2.2.5	Priming function (Alarm at about 16 secs.)	_____	_____
5.2.2.6	Delivery function (RV displayed)	_____	_____
5.2.2.7	Occlusion alarm function (finger pressure)	_____	_____
5.2.2.8	Alarms		
5.2.2.8.1	Near Empty	_____	_____
5.2.2.8.2	Empty	_____	_____
5.2.2.9	Reset volume switch function	_____	_____
5.2.2.10	Light switch function	_____	_____
5.2.2.11	Motor noise B-D 60cc at 60 ml/hr for one min.	_____	_____
5.2.3	OPERATIONAL CHECKS (in AC Mode):		
5.2.3.1	Power Up	_____	_____
5.2.3.2	Programmable	_____	_____
5.2.3.3	Verify backlight to illuminate	_____	_____
5.2.3.4	Uninterrupted function when AC power is disconnected	_____	_____
5.2.3.5	Charging function	_____	_____
5.2.3.6	Sign/Date	_____	
5.2.4	TRANSDUCER CALIBRATION CHECK:		
5.2.4.1	Program in Q.C. Test Mode - Code 1000	_____	_____
5.2.4.2	1.5±.5_____, 8.0±.75_____, 15.0±1.5_____		
5.2.5	POSITION SENSOR CALIBRATION		
5.2.5.1	1st reading: 0=_____HEX=_____ 4.836±.005=_____HEX=_____ 2nd reading: Lowest point = _____HEX=_____ Highest point =_____HEX_____ Lowest point HEX number must be equal to or less than 0 reading HEX number, by 1 HEX digit only. Highest point HEX number must be equal to or greater than 4.836 reading HEX numbef, by 1 HEX digit only.	_____	_____
5.2.5.2	Sign/Date	_____	

S/N _____

5.2.6 SYRINGE RECOGNITION TEST (SEE FORM P-72-20003-0-X, P-72-20004-0-X OR P-72-20005-G-X IF APPLICABLE)

5.2.6.1	MFG/SIZE	LOW	HI	ACCEPT	REJECT
	No Syringe	088	115	_____	_____
	TERUMO				
	1 ML	145	171	_____	_____
	5 ML	461	531	_____	_____
	20 ML	790	860	_____	_____
	60 ML	1188	1258	_____	_____

5.2.6.2 Sign/Date _____

5.2.7 FLOW TEST (See Flow Test Procedure, 4-72-FLOW-0-X)

5.1.7.1	Syr. Type	Syr. Size	Tubing Type	Rate	Elapsed Time	Predict Volume	Deliver Volume	± 3% Error
	_____	_____	_____	_____	_____	_____	_____	_____
	_____	_____	_____	_____	_____	_____	_____	_____

5.2.7.2 Sign/Date _____

2.8 FINAL CHECK:

5.2.8.1	Screw covers (4) and tamper label (1) attached	ACCEPT	REJECT
		_____	_____

COMMENTS: _____

_____

_____

_____

Accept Reject
(Circle One)

_____
Inspector/Date

P-72-20001-0-6
DCN#: 91053002

RE J. Ammann 5-31-91 MFG B Keating 6-14-91 QC [illegible] 6/14/91

BATCH FUNCTIONAL TEST
MODEL 2001

Date(s) of Inspection:	PROCEDURE	List S/N No. By Software version:
Batch Size:	Inspect all pumps using form P-72-20001-0-X (Latest revision) Flow test a random sample using special level S4 reduced. IGNORE AQL. No. flow tested:	
Work Order No.:		

Flow tests:

S/N	Syringe Type	Syringe Size	Tubing Type	Rate	Elapsed Time	Predicted Volume	Delivered Volume	± 3% Error

COMMENTS:

P-72-20002-0-1
DCN90070201

Approval [signature] Date 7/27/90

Approval [signature] Date 7-31-90

Accept / Reject (Circle)

Inspector Date

Reviewer Date

TITLE: Q.C. Final Test Procedure, Model 2010	PAGE 1 OF 6
SPECIFICATION: 4-72-21001-0-1	REVISION: 1

1.0 PURPOSE:

1.1 To establish a detailed test procedure to demonstrate that the Model 2010 meets inspection specifications.

2.0 SCOPE:

2.1 The Q.A. Inspector is responsible for the inspection, acceptance/rejection and notifying accounting.

2.2 The electronics technician will test the pumps prior to sampling by Q.C.

2.3 The Director of Quality Assurance (or designate) is responsible for assuring compliance with this procedure.

3.0 RELATED PROCEDURES AND DOCUMENTS:

3.1 Form P-72-21001-0-X, Q.C. Test Report Form (X = Latest revision)

3.2 Associated Assembly Specifications

3.3 Model 2010 Operator's Manual

3.4 Form P-72-21002-0-X, Batch Functional Test

3.5 Form P-72-20004-0-X or P-72-20005-G-X Syringe Recognition Test (if applicable)

3.6 GMP Regulations

3.7 MIL-STD-105D

3.8 Syringe Infusion Pump Flow Test Procedure, 4-72-FLOW1-0-X

4.0 ASSOCIATED MATERIALS:

4.1 Hand tools

4.2 AC power source

4.3 Force transducer test gauge

5.0 PROCEDURE:

5.1 Pumps are delivered to Q.C. by production in batches. Several batches may make up a work order. Record on inspection forms: P-72-21001-0-X and P-72-21002-0-X (where appropriate). See 4-61-20010-G-X for German Screen Translations (if applicable).

5.1.1 Identify pump model/serial number.

5.1.2 Record the work order on the inspection form.

5.1.3 The Q.C. Inspector will test per forms P-72-21001-0-X and P-72-21002-0-X.

5.2 Inspection procedure

5.2.1 Visual Inspection

5.2.1.1 Inspect for presence of S/N-UL label and Charger label on pump's rear panel, checking for legibility and record serial number on the Inspection Form.

5.2.1.2 Rubber bumpers are attached to the bottom (4 each).

5.2.1.3 Check for front panel's printing and legibility.

5.2.1.4 On/off switch is oriented with the "1" towards the slide.

5.2.1.5 Check overall cosmetic appearance. No finger print on LCD window.

5.2.1.6 Turn unit on all sides and check for any loose parts both internal and external.

5.2.2 Operational Checks: Battery Mode

5.2.2.1 Check syringe slide operation. With clutch disengaged, carriage must slide freely along it's full travel with no appreciable friction or binding. Clutch should freely disengage and spring back into engagement.

5.2.2.1.1 Syringe Plunger Retainer should be firmly attached to Syringe Driver.

5.2.2.2 Check for proper lift and function of the syringe clamp. For German Pump, use German syringes. Clamp must lock onto syringe tabs.

5.2.2.3 With unit unplugged from AC power, turn the power switch on. After checks, unit should be in program mode with "battery in use" (German: "BATT. Betrieb") light illuminated. Record on the top of the form the software version, the battery voltage, the alarm delay and the number of the options. Use overlay and manual with German displays added for German version.

Observe for:

5.2.2.3.1 Proper software revision
5.2.2.3.2 Proper power-up system check
5.2.2.3.3 Alarms sound quality and volume
5.2.2.3.4 LED's function
5.2.2.3.5 LCD display contrast

5.2.2.4 Programming - Select mode (ML/HR, volume/time, MG/HR or Body weight mode), Bolus amt (yes or no), syringe manufacturer, load syringe, bolus amt, rate. Verify operation of all keys used during this sequence. The pumps may be preprogrammed to exclude certain options. Vary the modes, manufactures and rates for different pumps.

5.2.2.5 Push and hold "prime" key until continuous audio alarm sounds (about 16 seconds). (Display should indicate PRIME VOL = XX.XX ML.) Verify visually syringe cradle movement.

5.2.2.6 Press "deliver" key. Unit should begin moving the syringe cradle, and incrementing the Total Volume delivered display. Pre-programmed Bolus amt should also be displayed.

5.2.2.7 Test the occlusion alarm. While in the deliver mode apply hand pressure to the end of the slide that meets the syringe plunger to activate the occlusion alarm. The pressure required to activate the alarm will vary with the syringe size, less is needed for the small syringe sizes and more is needed for the larger sizes.

5.2.2.8 Test Bolus function by pressing the "Bolus" and "Prime" keys. Bolus amt. and total vol. delivered should be displayed.

5.2.2.9 Resume the deliver mode, run cradle through "near empty" to "empty" alarms and verify alarm function.

5.2.2.10 After empty alarm, pressing "reset total volume" button should change the "Total Volume" display to 0.0000.

5.2.2.11 Check motor for noise using a B-D 60cc at 60 ml/hr for 1 minute. Reject pump if excessive noise is observed.

5.2.3 Operational Checks: AC Mode

5.2.3.1 Plug unit in AC receptacle, and turn power switch off, then on. Unit should go through power up sequence as in 5.2.2.3, except that "battery in use" LED should be off, and "battery charging" LED should be on.

5.2.3.2 Verify unit programs properly, as in 5.2.2.4. Place in deliver mode.

5.2.3.3 Verify backlight to illuminate in the AC mode. You may need to turn off the room lights to check this.

5.2.3.4 Turn the AC power off, leaving the unit's power switch on. No interruption in function should occur, but the "battery in use" LED should illuminate.

5.2.3.5 Turn the unit's power switch off. Plug in AC receptacle, and depress and hold "stop/program" and "deliver" keys simultaneously while turning the units power switch to on. Unit should display "BATTERY TIME= 00:00". After one minute the LCD will display "BATT.V= X.X".

5.2.3.6 The inspector performing the testing signs and dates the form.

5.2.4 Transducer Calibration Check

5.2.4.1 Press stop/program and select key at the same time, turn pump on, hold for approximately one second and release. Lock = 000.0 will appear on the display. Key in 100.0 onto the display. Press enter. Access complete. Display will show "Force (lb) 00.XX=XX".

5.2.4.2 Test the occlusion pressure using the 2001 force gauge. Place gauge on the pump, and set gauge to the values stated on the "Q.C. Final Test Report, Model 2010". The 2010 Pump display should read within the stated tolerances.

5.2.4.2.1 The tolerances are as follows:
1.5±.5,
8.0±.75,
15.0±1.5.

5.2.5 Position Sensor Test (This test should be done with the clutch disengaged.)

5.2.5.1 Press the stop/program key once. Pos. (inch) appears on display. For the first readings, move track so that 0.000 is shown on the display. Record this number and its corresponding HEX number. Move track so that 4.836±.005 is shown on the display. Record this # and its corresponding HEX #. For the second readings, move the track to the lowest point possible. Record this # and its corresponding HEX #. Move the track to the highest point possible. Record this # and its corresponding HEX #. Verify that the lowest point HEX # is equal to or less than the 0 reading HEX # by one HEX digit only. Verify that the highest point HEX # is equal to or greater than the 4.836 reading HEX # by one HEX digit only.

5.2.5.2 The inspector performing the testing signs and dates the form.

5.2.6 Syringe Recognition Test

5.2.6.1 Press the stop/program key once again. Size (inch) will appear on the display.

Insert syringes listed on "Syringe Recognition Report, P-72-20004-0-X or P-72-20005-G-X, if applicable. Read number on display between high and low for each syringe.

5.2.6.2 The inspector performing the testing signs and dates the form.

5.2.7 Flow Test

5.2.7.1 Perform flow testing as required on form P-72-21001-0-X or P-72-21002-0-X. Use any size syringe in the volume/time mode. Test should last 20 minutes mimimum using more than 70% of the pipette. Refer to Flow Test Procedure 4-72-FLOW1-0-X.

5.2.7.2 The inspector performing the testing signs and dates the form.

5.2.8 Physicial Test

(Inspection level S4 Ignore AQL) Access each mode, Volume/Time, ML/Hr, Mg/HR and Body weight.

5.2.8.1 Verify MG/Kg/min, MG/Kg/HR, Mcg/Kg/min and Mcg/Kg/HR are accessible.

5.2.9 Final Check

5.2.9.1 Check for presence of screw covers over 4 screws. Two in line with the brass pole mount inserts and two screws closest to the face plates. Check for tamper evident label on screw on the back bottom center.

5.3 Inspection Forms

5.3.1 Fill in the Inspection Form, P-72-21001-0-X for Model 2010, for all test categories. Note any improper function in the reject column and comments section. Any reject must be separated and handled in accordance with the Q.A. Manager's instructions. The form must be signed and dated.

5.3.2 Form number P-72-21002-0-X, Batch Functional Test - Model 2010, should also be completed for each batch of pumps delivered to Q.C. Instructions are on the form.

Q.C. Final Test Report, Model 2010
Preprogrammed Settings:

(See Procedure 4-72-21001-0-X)

S/N_____

Software Version_____ _____ _____ _____ _____
Work Order:_____ Alarm Vol. Alarm Delay Batt. V. Options

	Accept	Reject
5.2.1 VISUAL:		
5.2.1.1 S/N-UL Label and Charger Label attached	_____	_____
5.2.1.2 Rubber bumpers attached (4)	_____	_____
5.2.1.3 Face plate printing and I.D.	_____	_____
5.2.1.4 On/off switch properly oriented	_____	_____
5.2.1.5 Overall appearance	_____	_____
5.2.1.6 Loose parts - internal and external	_____	_____
5.2.2 OPERATIONAL CHECKS:		
5.2.2.1 Syringe slide function	_____	_____
5.2.2.1.1 Syringe plunger retainer attached	_____	_____
5.2.2.2 Syringe clamp function	_____	_____
5.2.2.3 Power switch function	_____	_____
5.2.2.3.1 Proper software revision	_____	_____
5.2.2.3.2 Proper power up system check	_____	_____
5.2.2.3.3 Alarms sound quality and volume	_____	_____
5.2.2.3.4 LED's function	_____	_____
5.2.2.3.5 LCD display contrast	_____	_____
5.2.2.4 Programmable	_____	_____
5.2.2.5 Priming function (Alarm at about 16 secs.)	_____	_____
5.2.2.6 Delivery function	_____	_____
5.2.2.7 Occlusion alarm function (finger pressure)	_____	_____
5.2.2.8 Bolus function	_____	_____
5.2.2.9 Alarms		
5.2.2.9.1 Near Empty	_____	_____
5.2.2.9.2 Empty	_____	_____
5.2.2.10 Reset volume switch function	_____	_____
5.2.2.11 Motor noise B-D 60cc at 60 ml/hr for one min.	_____	_____
5.2.3 OPERATIONAL CHECKS (in AC Mode):		
5.2.3.1 Power Up	_____	_____
5.2.3.2 Programmable	_____	_____
5.2.3.3 Verify backlight to illuminate	_____	_____
5.2.3.4 Uninterrupted function when AC power is disconnected	_____	_____
5.2.3.5 Charging function	_____	_____
5.2.3.6 Sign/Date	_____	
5.2.4 TRANSDUCER CALIBRATION CHECK:		
5.2.4.1 Program in Q.C. Test Mode - Code 1000	_____	_____
5.2.4.2 1.5±.5_____, 8.0±.75_____, 15.0±1.5_____		
5.2.5 POSITION SENSOR CALIBRATION		
5.2.5.1 1st reading: 0=_____HEX=_____4.836±.005=_____HEX=_____		
2nd reading: Lowest point =_____HEX=_____ Highest point_____HEX=_____		
Lowest point HEX number must be equal to or less than 0 reading HEX number, by 1 HEX digit only.		
Highest point HEX number must be equal to or greater than 4.836 reading HEX number, by 1 HEX digit only.	_____	_____
5.2.5.2 Sign/Date	_____	

S/N _____

5.2.6 SYRINGE RECOGNITION TEST (SEE FORM P-72-20003-0-X, P-72-20004-0-X OR P-72-20005-G-X IF APPLICABLE)

5.2.6.1 MFG/SIZE	LOW	HI	ACCEPT	REJECT
No Syringe	088	115	_____	_____
TERUMO				
1 ML	145	171	_____	_____
5 ML	461	531	_____	_____
20 ML	790	860	_____	_____
60 ML	1188	1258	_____	_____

5.2.6.2 Sign/Date _____

5.2.7 FLOW TEST (See Flow Test Procedure, 4-72-FLOW-0-X)

5.2.7.1 Syr. Type	Syr. Size	Tubing Type	Rate	Elapsed Time	Predict Volume	Deliver Volume	± 3% Error
_____	_____	_____	_____	_____	_____	_____	_____
_____	_____	_____	_____	_____	_____	_____	_____

5.2.7.2 Sign/Date _____

5.2.8 PHYSICAL TEST: Access modes (Special level 4 inspection, ignore AQL)

5.2.8.1 Verify 4 body weight

Sub-modes	ACCEPT	REJECT
	_____	_____

5.2.9 FINAL CHECK:

5.2.9.1 Screw covers (4) and tamper label (1) attached	ACCEPT	REJECT
	_____	_____

COMMENTS: _____

_____

_____

_____

Accept Reject
(Circle One)

_____
Inspector/Date

P-72-21001-0-2
DCN #: 91053002

RE U. Ammann 5-31-91 MFG B Keating 6-14-91 QC [illegible] 6/14/91

BATCH FUNCTIONAL TEST
MODEL 2010

Date(s) of Inspection:	PROCEDURE	List S/N No. By Software version:
Batch Size:	Inspect all pumps using form P-72-21001-0-X (Latest revision) Flow test a random sample using special level S4 reduced. IGNORE AQL. No. flow tested:	
Work Order No.:		

Flow tests:

S/N	Syringe Type	Syringe Size	Tubing Type	Rate	Elapsed Time	Predicted Volume	Delivered Volume	± 3% Error

COMMENTS:

P-72-21002-0-0
DCN90110101

Approval Changjo Lee Date 12/20/90

Approval D. Parker Date 12-21-90

Accept / Reject (Circle)

Inspector Date

Reviewer Date

TITLE: Q.C. FLOW TEST PROCEDURE FOR ALL SYRINGE INFUSION PUMPS	PAGE 1 OF 2
SPECIFICATION: 4-72-FLOW1-0-0	REVISION: Orig.

1.0 PURPOSE:

1.1 To establish a detailed test procedure to demonstrate that the syringe infusion pumps meet the proper flow rate accuracy specifications.

2.0 SCOPE:

2.1 The Q.A. Inspector is responsible for the testing, acceptance/rejection.

2.2 The Director of Quality Assurance (or designate) is responsible for assuring compliance with this procedure.

3.0 RELATED PROCEDURES AND DOCUMENTS:

3.1 Form P-72-01001-0-X, P-72-20001-0-X or P-72-21001-0-X, Q.C. Test Report Forms (X = Latest revision)

3.2 Work order

3.3 Pumps Operator's Manual

3.4 Form P-72-01002-0-X, P-72-20002-0-X or P-72-21002-0-X, Batch Functional Test Forms (X = Latest revision)

4.0 ASSOCIATED MATERIALS:

4.1 BD, Monoject and Terumo Syringes

4.2 53-60-225 MFI Extension Sets

4.3 Distilled Water

4.4 Various sizes of calibrated pipets

5.0 PROCEDURE:

5.1 Pumps are delivered to Q.C. by production in batches. Several batches may make up a work order. Each batch must be tested on a Batch Functional. The number to be Flow tested will be determined by the batch size and the current Inspection Level.

5.1.1 Identify pump model/serial number.

5.1.2 Record the serial number on the inspection form.

5.1.3 Select any size syringe from BD, Mono, or Terumo. Plan to use more than 70% of the syringe. The

size of syringe selected will determine the size of pipet you should use. Try to use at least 70% of the pipet. 3cc syringes should use a 2 ml pipet, 6cc syringes should use a 5 ml pipet. 20-35cc syringes should use a 25 ml pipet.

5.1.4 Record the syringe type, syringe size and tubing type on the inspection form.

5.1.5 To determine the rate you must decide on the dose volume and the delivery time. The dose volume should be more than 70% of the syringe volume. The delivery time should be no less than 20 minutes. To calculate the rate, you will divide the dose volume by the delivery time. (Delivery time must be in decimal form). With the Models 2001 and 2010 the rate will be calculated by the program within the unit after the dose volume and delivery time are entered.

$$\text{Rate} = \frac{\text{Dose Vol.}}{\text{Del. Time}}$$

5.1.6 Record the rate, elapsed time and predicted volume on the inspection form.

5.1.7 Fill the syringe with Distilled water and connect to the Extension set. All air bubbles must be removed to insure an accurate flow test. If bubbles are in the tubing, prime them out before attaching to the pipet.

5.1.8 Load syringe into the syringe cradle and program unit for delivery in the Volume/Time mode. Prime unit to the first significant number on the pipet. Set a timer for the correct delivery time. Start the timer and the delivery. At end of delivery, record the delivered volume on the inspection form.

5.1.9 To determine the % error you will take the actual delivered volume and subtract the predicted or dose volume. Divide the difference by the predicted or dose volume and then multiply by 100. [(Actual - Dose Volume) divided by dose volume] * 100.

5.2 Record the % error on the inspection form.

APPENDIX F. SPARE PART LIST & TEST FIXTURES

Notes:

1. Part Number format: 0-AA-BBBBB-C-X, X is revision #
   X will be changed due to revision.
   Consult manufacturer for the appropriate revision level.

2. Refer to Assembly Drawing for Item # in Sub-Assemmbly.

MEDFUSION, INC.
2001/2010 SPARE PARTS LIST

PART NUMBER	ITEM NUMBER	DESCRIPTION
0-68-20M00-0-X		Pole Clamp Kit
0-72-20C07-0-X		Charger S/A
0-68-20A00-0-X		**Top Housing S/A (specify Software Version #)**
0-84-K2001-0-X	2	Keypad 2001
0-84-K2010-0-X	2	Keypad 2010
0-68-20C00-0-X	4	LCD Display S/A
0-68-20E01-0-X	5	Main Board S/A
0-68-20 --	10	MPU, Programmed (specify Software Version #) Consult factory for exact part number
0-87-1P5SB-0-0	N/A	Fuse, 1.5A slo-blo (soldered on Main Board)
0-48-20000-0-X	1	Top Housing
0-68-20A01-0-X		**Bottom Housing S/A**
0-48-20001-C-0	1	Bottom Housing
0-68-20C09-0-X	2	Battery Pack S/A
0-68-20C01-0-0	3	Power Switch S/A
0-48-20025-0-0	4	Switch Guard (need 2pcs per pump)
0-68-20C02-0-X	5	DIN Receptacle S/A
0-68-20C06-0-X	6	Alarm S/A
0-28-EC100-8-0	8	Strain Relief 8-pin
0-39-TT102-0-0	9	Wire Tie
0-49-20003-0-0	10	Rubber Bumper
0-68-20A02-0-X		**Slide Housing S/A**
0-68-20A04-0-X	2	Plunger Holder/Track S/A
0-48-20008-0-0	1.9	Plunger Holder/Insert (Ref. Dwg 1-68-20A04-0-X)
0-68-20A03-0-X	4	Slide S/A
0-79-14280-0-0	25	Main Cable
0-68-20C08-0-X	26	Stepper Motor S/A
0-48-20006-0-0	40	Syringe Clamp
0-68-20C04-0-X	30	Pot. S/A ✓
0-48-20013-0-0	34	Clamp Gear
0-50-20009-C-0	31	Torsion Spring
0-48-20019-0-0	35	Pot. Clamp
0-48-20020-0-0	32	Spring End Clamp
0-48-20024-0-0	28	Position Pot. Holder
0-48-20014-0-0	29	Position Pot. Gear
0-48-20015-0-0	8	Cluster Gear
0-39-13318-0-0	1	E-Clip
0-49-20001-0-1	22	Cable Seal
0-48-20031-0-0	23	Cable Seal Plug

MEDFUSION, INC.
2001/2010 SPARE PARTS LIST

PART NUMBER	ITEM NUMBER	DESCRIPTION
0-48-20011-0-0	18	Clutch, Upper Half
0-48-20012-0-0	17	Clutch, Lower Half
0-48-20018-0-X	19	Clutch Key
0-50-20008-0-0	16	Clutch Spring
0-50-20007-0-X	7	Clutch Actuator
0-48-20009-0-0	3	Clutch Lever
0-48-20016-0-0	6	Clutch Cover
0-50-20001-0-X	10	Leadscrew
0-48-20034-0-0	11	Leadscrew Thrust Bearing
0-48-20023-0-0	9	Leadscrew Bearing
0-48-20010-0-0	20	Worm Gear
0-39-13311-0-0	14	E-Clip, Leadscrew
0-68-20E02-0-X	24	Aux. Board S/A
0-48-20005-0-0	38	Slide Door
0-48-20027-0-0	46	Water Seal
0-49-20002-0-0	21	Clamp Seal
0-68-20A05-0-0	37	Worm/Coupling S/A
		Bottom Housing Hardware (REF 1-68-20A01-0-X)
0-42-90372-0-0	7	Screw, 4-40x3/8 Phil Pan HD SS
		Top Housing Hardware (REF 1-68-20A00-0-X)
0-42-90252-0-0	6	Screw, 4-40x1/4 Phil Pan HD SS
0-42-J1002-0-0	7	Hex Head, SS, 4-40x1.00
0-42-04503-0-0	8	Standoff, 3/16 Hex Male-Female
0-42-1653N-0-0	9	3/16 Round Female Standoff
0-42-4505B-0-0	12	3/16 Hex Male-Female Standoff
		Slide Housing S/A Hardware (REF 1-68-20A02-0-X)
0-42-80622-0-0	13	5/8 Set Screw 4-40x.625 SS
0-41-90502-0-0	33	Screw, Pan Phil HD, SS, 2-56x1/2
0-41-93122-0-0	36	Screw, Pan Phil HD, SS, 2-56x5/16
0-42-90252-0-0	5	Screw, Pan Phil HD, 4-40x1/4
0-42-G7701-0-0	27	3/16 Hex Female, Standoff
0-42-2098B-0-0	48	1/4 Hex Female Standoff
0-42-A0252-0-0	39	Screw, Flat HD Phil, SS 4-40
		Final Assembly Hardware (REF 1-72-20010-0-X)
0-42-A0502-0-0	8	4-40x1/2 Flat HD Ph SS
		Pole Clamp
0-43-A0372-0-0	N/A	Screw, 6x32x3/8 Flat HD, Ph, SS
		OTHER
A-61-205M1-0-0		2001/2010 Syringe Infusion Pump Service Manual

medfusion inc

APPENDIX G. TROUBLE-SHOOTING CHART

1.3

D. Connect Batt

Supply 7.7 VOLT

Red LEAD

Black LEAD

STOP Program / Select

108.9 cycles

7.7 volt after

7.3

[illegible]

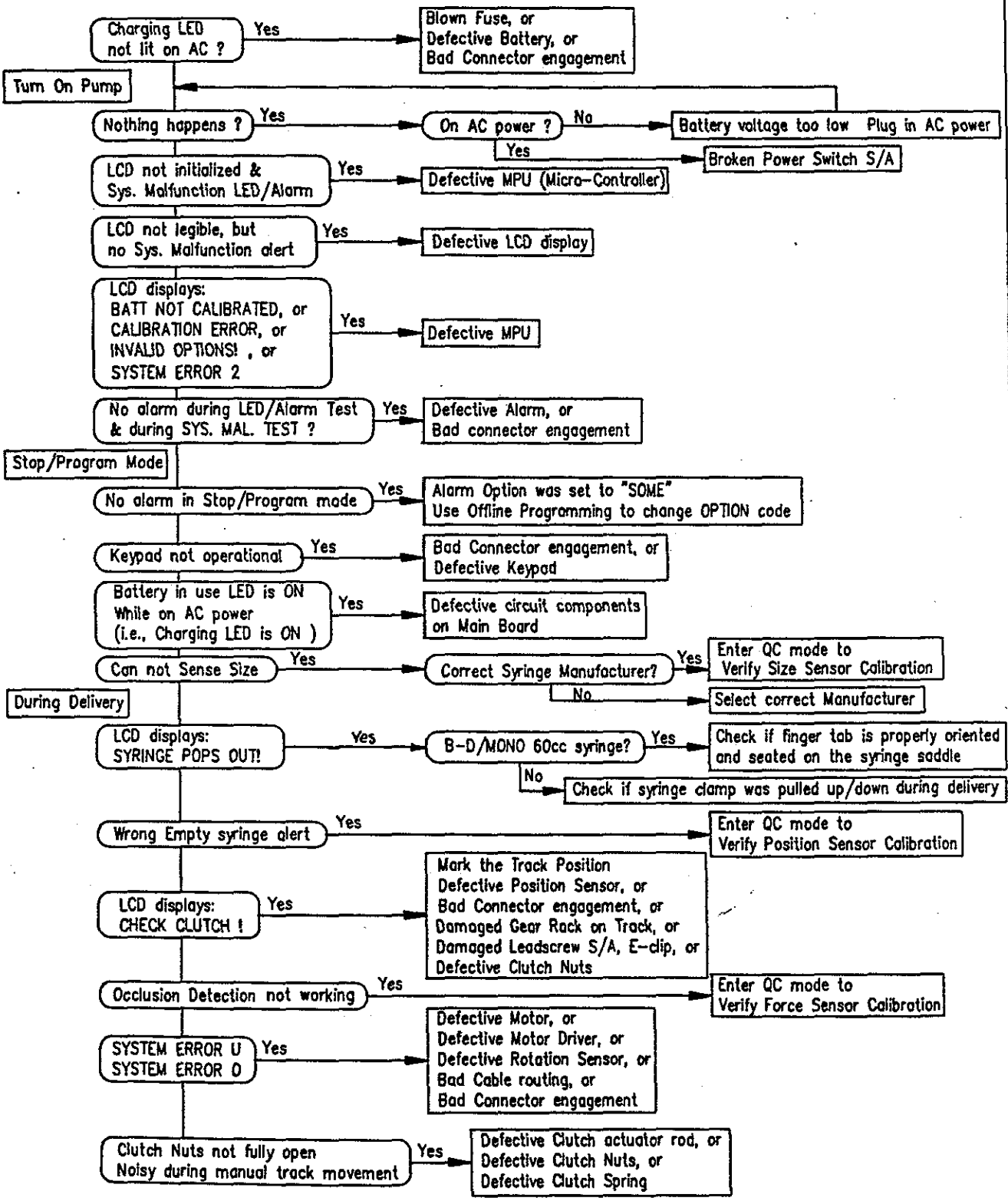
212-[illegible]

8021

711.3

399-2163

TROUBLE-SHOOTING CHART


Charging LED not lit on AC ?
Yes
Blown Fuse, or Defective Battery, or Bad Connector engagement
Turn On Pump
Nothing happens ?
Yes
On AC power ?
No
Battery voltage too low Plug in AC power
Yes
Broken Power Switch S/A
LCD not initialized & Sys. Malfunction LED/Alarm
Yes
Defective MPU (Micro-Controller)
LCD not legible, but no Sys. Malfunction alert
Yes
Defective LCD display
LCD displays: BATT NOT CALIBRATED, or CALIBRATION ERROR, or INVALID OPTIONS! , or SYSTEM ERROR 2
Yes
Defective MPU
No alarm during LED/Alarm Test & during SYS. MAL. TEST ?
Yes
Defective Alarm, or Bad connector engagement
Stop/Program Mode
No alarm in Stop/Program mode
Yes
Alarm Option was set to "SOME" Use Offline Programming to change OPTION code
Keypad not operational
Yes
Bad Connector engagement, or Defective Keypad
Battery in use LED is ON While on AC power (i.e., Charging LED is ON)
Yes
Defective circuit components on Main Board
Can not Sense Size
Yes
Correct Syringe Manufacturer?
Yes
Enter QC mode to Verify Size Sensor Calibration
No
Select correct Manufacturer
During Delivery
LCD displays: SYRINGE POPS OUT!
Yes
B-D/MONO 60cc syringe?
Yes
Check if finger tab is properly oriented and seated on the syringe saddle
No
Check if syringe clamp was pulled up/down during delivery
Wrong Empty syringe alert
Yes
Enter QC mode to Verify Position Sensor Calibration
LCD displays: CHECK CLUTCH !
Yes
Mark the Track Position Defective Position Sensor, or Bad Connector engagement, or Damaged Gear Rack on Track, or Damaged Leadscrew S/A, E-clip, or Defective Clutch Nuts
Occlusion Detection not working
Yes
Enter QC mode to Verify Force Sensor Calibration
SYSTEM ERROR U SYSTEM ERROR D
Yes
Defective Motor, or Defective Motor Driver, or Defective Rotation Sensor, or Bad Cable routing, or Bad Connector engagement
Clutch Nuts not fully open Noisy during manual track movement
Yes
Defective Clutch actuator rod, or Defective Clutch Nuts, or Defective Clutch Spring

TROUBLE-SHOOTING CHART